Exhibit A

Efficacy of Ultreo in Dental Plaque Removal

Sharma NC, Qaqish J, Galustians J, Ortblad K
BioSci Research Canada Ltd., Mississauga, Ontario; Ultreo, Inc., Redmond, Washington

Print This Abstract

Objective

To evaluate plaque removal efficacy of Ultreo after 1 and 2 minutes of brushing.

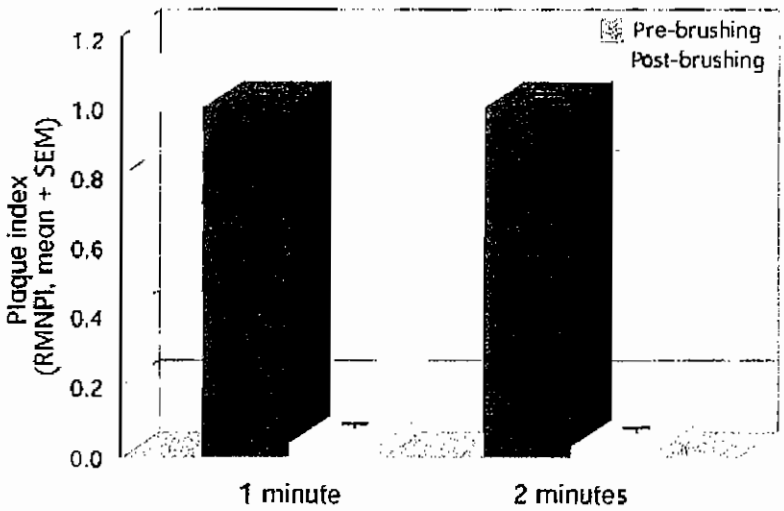
Methods

In a 2-visit, examiner-blinded, crossover study; thirty-three subjects with a pre-brushing plaque score of ≥0.6 determined by the Refined Modified Navy Plaque Index (RMNPI) were enrolled. Subjects refrained from all oral hygiene 23 -25 hours prior to all study visits and were randomly assigned to one of two treatment arms (Ultreo for 1 minute or 2 minutes). Pre- and post-brushing plaque scores were obtained, an intraoral examination (soft and hard tissue) performed, and a product evaluation questionnaire completed at each study visit.

Results

Thirty-three subjects completed the study. The oral examination at each study visit indicated normal findings and no adverse events were reported during the study. The percentage reduction in full mouth plaque (single brushing) was 86.0% and 87.6% after 1 and 2 minutes of brushing with the Ultreo, respectively. Changes in plaque reduction from pre-brushing were statistically significant ($p<0.001$) for both treatments. The percentage plaque reduction was 95.5% and 96.8% for interproximal surfaces after 1 and 2 minutes of brushing, respectively, and 76.4% and 78.5% for the gumline surfaces after 1 and 2 minutes of brushing, respectively. Furthermore the percentage reduction of posterior plaque was 84.1% and 85.2% for 1 and 2 minutes of brushing respectively. Reductions in interproximal, gumline, and posterior plaque were significant ($p<0.001$). Positive comments noted from the questionnaire included an overall clean feeling after brushing and a gentle bristle motion.

Figure 1: Interproximal Plaque



Conclusions

- Use of Ultreo for both 1 minute and 2 minutes resulted in a significant reduction in plaque.
- Ultreo removed up to 95% of plaque from hard-to-reach interproximal areas during the first minute of brushing.
- Ultreo was effective in removing plaque from all surfaces including interproximal, gumline, and posterior regions.

- Subjects using the Ultreo expressed an immediately feeling of clean teeth after brushing.

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Exhibit B

Efficacy and Safety of Ultreo in a Population with Mild to Moderate Gingivitis

Goyal CR, Qaqish J, Galustians J, Ortblad K
BioSci Research Canada Ltd., Mississauga, Ontario; Ultreo, Inc., Redmond, Washington

Print This Abstract

Objective

To evaluate the efficacy and safety of Ultreo over a 30-day period in a population with mild to moderate gingivitis.

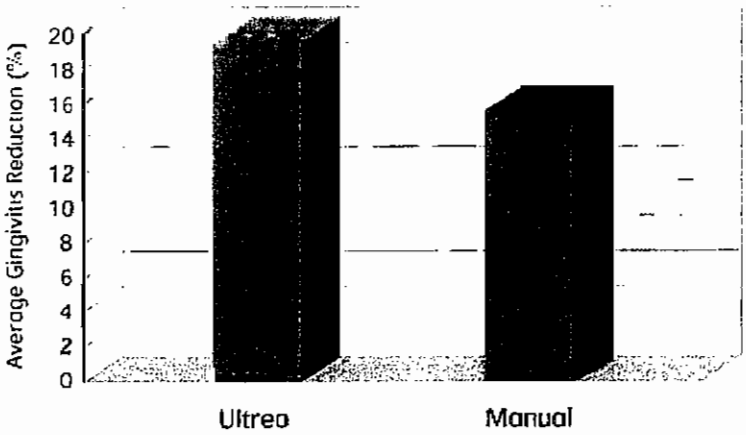
Methods

This 30-day, randomized, examiner blinded, parallel-arm study evaluated 53 subjects (n=26 Ultreo, n=27 Oral-B 35 manual toothbrush) with a minimum of 18 natural teeth and a Löe and Silness Gingival Index of =1.5. An intraoral examination (oral soft and hard tissues, restorations) and a Löe and Silness Gingival Index were recorded at baseline and 30 days. Subjects were instructed to brush at home twice per day with their assigned toothbrush and study toothpaste. A product evaluation questionnaire was also completed at the 30-day study visit.

Results

The oral examinations indicated normal findings at all time points for both groups and no adverse events were reported during the study. There were no significant differences in gingivitis scores at baseline between the toothbrush groups ($p>0.05$). From baseline each treatment group demonstrated a significant reduction in gingivitis over the 30-day period ($p<0.001$). However, subjects using Ultreo demonstrated a significantly greater reduction in gingivitis compared to those using the manual toothbrush ($p=0.010$). Results from the questionnaire, on average, indicated subjects using the Ultreo experienced a long-lasting immediate clean feeling after brushing and, by the end of the study, perceived improved gingival health.

Figure 1: Average gingivitis reduction after 30 days.



Conclusions

- Ultreo was shown to reduce gingivitis in 30 days.
- Ultreo was significantly more effective in reducing gingivitis than a manual toothbrush.
- Subjects using the Ultreo perceived clean teeth and improved gingival health.
- Both toothbrushes were found to be safe as no adverse events were reported.

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Exhibit C

Assessing the Ability of Ultreo to Remove Extrinsic Surface Stain from the Teeth

1. Goyal CR, Qaqish J, Galustians J, Ortblad K
BioSci Research Canada Ltd., Mississauga, Ontario; Ultreo, Inc., Redmond, Washington
2. Baltuck C, Ortblad K, McInnes C
Ultreo, Inc. Redmond, Washington

Print This Abstract

Objective

To assess the ability of Ultreo to reduce extrinsic stains on the surface of teeth after 2 and 4 weeks of use.

Methods

Twenty-two subjects with an average baseline Lobene stain index of ≥2 were enrolled in a 4 week, randomized, examiner-blinded, parallel designed study (n=17 Ultreo, n=5 Oral-B 35 manual). The purpose of the unbalanced control group was to maintain the examiner blinding to treatment. Subjects were instructed to brush twice per day with the study toothbrush and study toothpaste. Lobene stain index scores were obtained and soft and hard tissue was evaluated at baseline, 2 and 4 weeks. A product evaluation questionnaire was also completed at the 4-week study visit.

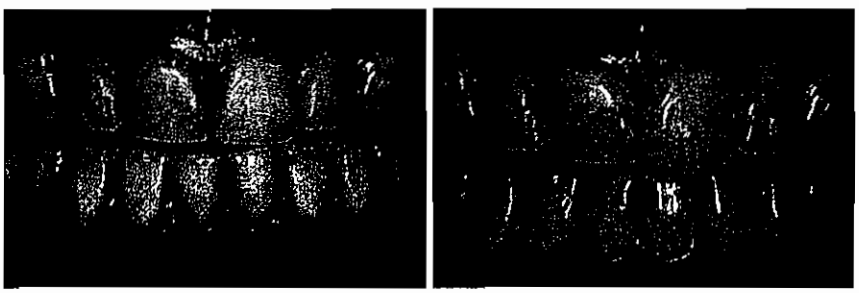
Results

There were no adverse events reported during the study and the oral examinations indicated normal findings at all time points. Use of the Ultreo resulted in a significant reduction in extrinsic stain (composite score, stain area, and stain intensity) from baseline as assessed by the Lobene Stain Index after both 2 and 4 weeks of use ($p<0.001$). The reduction in stain was significant both on the body of the tooth and along the gingival margin ($p<0.005$). In addition to the objective measures, the questionnaire at the end of the study indicated that subjects using the Ultreo felt they had whiter teeth and any remaining stain was smaller in area and lighter in intensity.

Conclusions:

- Ultreo effectively reduced extrinsic stain from baseline after 2 and 4 weeks of use.
- Ultreo was found to be safe as no adverse events were reported.
- Subjects perceived less stain after using Ultreo.

Figure 1. Coffee, tea and chlorhexidine induced stain at baseline and 7 days after using Ultreo twice daily as demonstrated in a separate case study (2).



a) Baseline b) 7 Days

Conclusions

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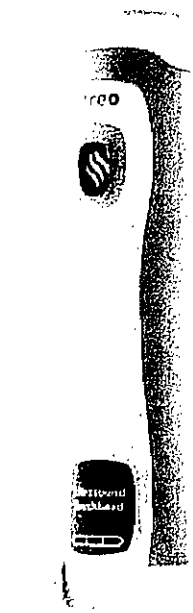

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Exhibit F

Evaluation of Ultrasound as a Means to Remove *Streptococcus mutans* Biofilm

Roberts FA, Hacker B, Oswald T, McInnes C
University of Washington, Seattle, WA; Ultreo Inc. Redmond WA

Print This Abstract

Objective

The objective of this study was to evaluate the ability of Ultreo's combined sonic and ultrasound processes to remove *S. mutans* biofilm.

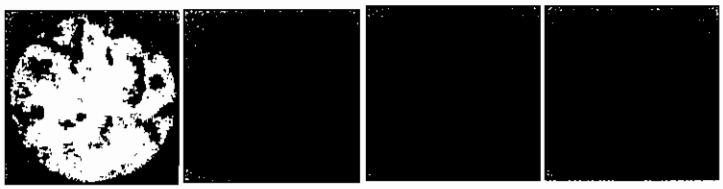
Methods

Dental plaque was modeled with a *Streptococcus mutans* biofilm grown (48 hrs) on either hydroxyapatite (HA) discs (5 mm) or frosted glass slides with grooves (0.2mm wide, 0.75mm deep). The biofilm was exposed to treatment either a) Ultreo, b) sonic brush (Sonicare Elite), c) oscillating brush (Oral-B Triumph), or d) control (Ultreo with ultrasound disabled). Additional surfaces were used for positive (biofilm with no treatment) and negative (no biofilm) controls. HA discs were positioned on average 3 mm from the active cleaning surface (bristle tips or ultrasound waveguide) within a dentifrice slurry. The surfaces of the grooved slides were directly brushed with the bristle tips within a dentifrice slurry. Biofilm was disclosed with either red or fluorescent dye prior to capturing images of the exposed surfaces. Images were examined visually and, for the HA discs, processed via image analysis for quantification of the treatment effect. Removal of biofilm from the disc was expressed as a percentage of the known plaque bacteria present (difference between positive and negative controls).

Results

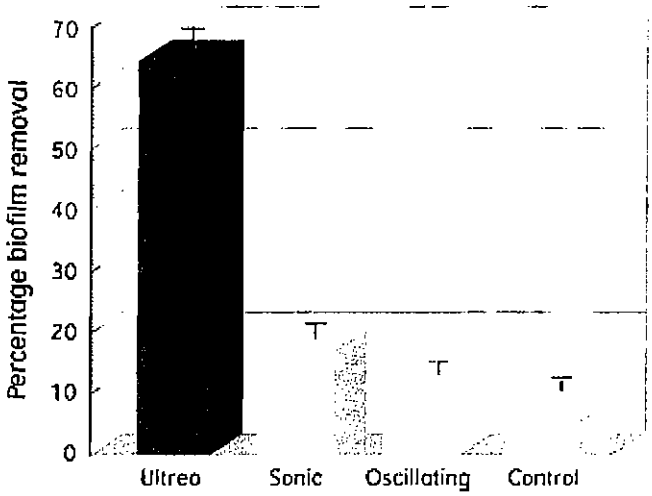
Representative images of HA discs exposed without bristle contact are provided in Figure 1. Biofilm was observed to either be removed such that the white disc surface could be seen (Fig. 1a) or thinned (Fig. 1b-d). Quantification of the removal from the HA discs is presented in Figure 2. Statistical analysis (ANOVA) of this data indicated a significant treatment effect ($p<0.001$). A Bonferroni post hoc test indicated that only Ultreo was significantly different than the other treatments ($p<0.001$).

Figure 1: Representative images of HA discs exposed without bristle contact to the disc surface



(a) Ultreo (b) Sonic (c) Oscillating (d) Control

Figure 2: Quantification of bacteria removed from HA discs via image analysis



For the grooved slides, bristle contact removed biofilm from the slide surface whereas biofilm within the grooves was observed to be substantially removed by the Ultreo and removed to a considerably lesser extent by other treatments (Figure 3).

Figure 3: Representative images of grooved slides exposed with bristle contact to the slide surface.

(a) Ultreo (b) Sonic (c) Oscillating (d) Control

Conclusions

- Ultreo was shown to remove significantly more *S. mutans* from HA discs without bristle contact than other power brushes.
- Ultreo's combined sonic and ultrasound activity removed *S. mutans* from grooved surfaces.

Clinical relevance of these results has not been established.
This research was supported in part by National Institutes of Health grant 2R44 DE016761-02.

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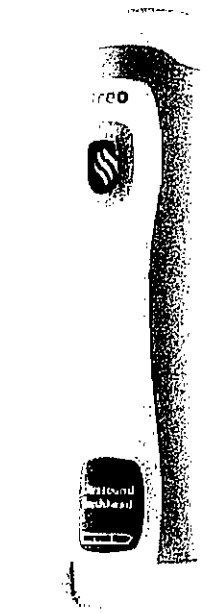

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Exhibit G

In Vitro Evaluation of Interproximal Biofilm Removal with Power Toothbrushes

Abstract

The purpose of this study was to evaluate and compare the efficacy of interproximal plaque removal between 2 power toothbrushes, the Sonicare FlexCare (FlexCare) and the Oral-B Professional Care 9000 Triumph (Triumph). An in vitro tooth model was used to evaluate the brushing efficacy of both active toothbrushes in removing dental plaque biofilm from the interproximal spaces of mandibular molar teeth, which are typically beyond the reach of toothbrush bristles. Microcosmic oral biofilms from pooled saliva were grown in a constant depth film fermenter for 8 days on hydroxyapatite (HA) disks. Disks were then inserted between a pair of molar teeth in the tooth model 2 mm to 4 mm from the bristle tips. Toothbrushing was performed for 15 seconds with no direct contact made between the bristles and the plaque biofilms on the HA disks. Plaque removal efficacy was determined by the percentage of viable bacteria removed from the disks as a result of brushing. The active FlexCare toothbrush removed a significantly higher percentage of biofilm bacteria compared with the inactive state ($P < .0001$) and with the active Triumph toothbrush ($P = .0001$). Moreover, the active FlexCare toothbrush had a slightly greater than 3-fold plaque removal efficacy compared with the active Triumph toothbrush.

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Dental plaque is a multispecies biofilm of microorganisms that grows as an ecosystem on hard and soft tissues in the oral cavity.[1-3] Biofilm formation is most prevalent on the hard tissues, particularly tooth enamel. Regular removal of dental plaque is essential for maintaining oral health. Uncontrolled proliferation of bacteria in the oral biofilm, often as a result of an ecological imbalance, can lead to caries, gingivitis, and even periodontal disease.[2,3]

A variety of oral hygiene products geared toward removal of dental plaque and prevention of further biofilm accumulation have been developed. Such products are intended to supplement regular toothbrushing. Dental plaque is mechanically removed via direct contact and movement of toothbrush bristles across tooth and gum surfaces. Control of toothbrush movement can be manual or through the use of mechanically powered toothbrushes that generate uniform bristle motion. The use of dental floss or proxibrushes to remove dental plaque is also based on their direct contact with plaque on tooth surfaces.[4]

One constant problem encountered in oral hygiene is dealing with plaque removal in hard-to-reach areas of the oral cavity, such as the interproximal regions and posterior teeth. Oral irrigators, which project a high-velocity fluid jet to shear away dental plaque in interproximal surfaces, are not always effective.[4] Power toothbrushes were originally

developed so that specific brush head movements (vibrations, rotations, or oscillations) would remove dental plaque via direct physical contact between the bristles and tooth surface.[4,5] The Sonicare[a] toothbrush integrated direct mechanical brushing with increased bristle velocity, increased brush stroke frequency (at 260 Hz), and novel brush head movements to generate localized hydrodynamic shear forces in the mouth. The combination of direct mechanical brushing and fluid dynamic activity improved targeted plaque removal efficacy, particularly in these hard-to-reach proximal areas. Clinical studies have demonstrated superior performance of the Sonicare toothbrush over a manual toothbrush in removing supragingival plaque in interproximal surfaces.[6,7]

Early studies providing evidence that fluid forces induced by Sonicare toothbrushes removed oral biofilm from dental surfaces were derived from in vitro models.[8-10] As methodology developed, the biofilm was placed in the interproximal space of a typodont model to specifically assess dental plaque removal efficacy in areas ordinarily inaccessible by toothbrush bristles.[11] Subsequent in vitro studies showed that the fluid forces associated with the Sonicare toothbrushes removed significantly more interproximal biofilm than rotating–oscillating power toothbrushes.[12-14]

The purpose of this study was to evaluate interproximal biofilm removal of the new Sonicare FlexCare power toothbrush with a contemporary rotating–oscillating power toothbrush using a proven in vitro biofilm model.[12,15]

Materials and Methods

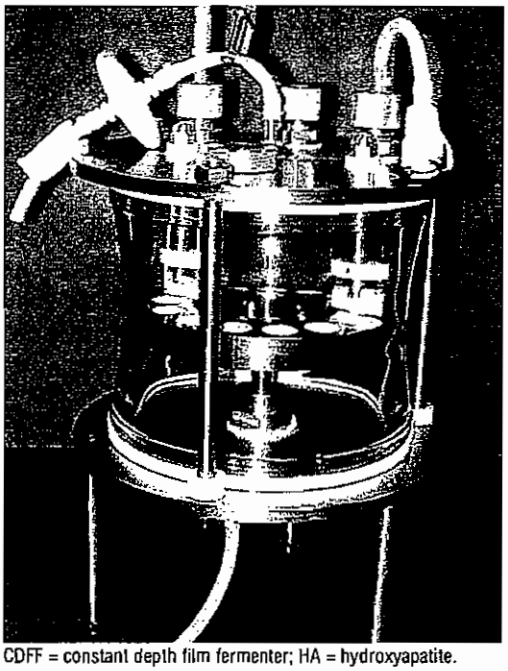
The biofilm removal test closely adhered to the methodology employed by Hope and Wilson.[12] This methodology was developed to evaluate the ability of fluid-induced forces generated by power toothbrushes to remove dental plaque biofilm from interproximal surfaces beyond the reach of the bristle. The model employs a constant depth film fermenter (CDFF) (Figure 1). The CDFF has been shown to produce steady-state oral biofilm communities and plaque structures similar to those occurring on the tooth surface.[16,17] The CDFF biofilm provides a measure of the ability of an oral hygiene device to remove plaque biofilm accumulated in interproximal spaces.

Treatment Arms

Three treatment arms were used in this test: the new Sonicare FlexCare (FlexCare) power toothbrush with the ProResults standard brush head as the test device; the Oral-B Triumph Professional Care 9000 (Triumph)[b] with the FlossAction brush head as a comparative rotating–oscillating power toothbrush; and an inactive control, the FlexCare toothbrush, switched off so there was no bristle movement. Any biofilm bacteria removed in this control arm represent bacteria spontaneously released from the biofilm surface as a result of non–bristle-induced forces within a fluid environment. The devices were tested without toothpaste, because active components within the toothpaste could alter bacterial viability.

[a]Philips Oral Healthcare, Inc; Snoqualmie, WA.

Figure 1—A model of the CDFF containing HA disks used to grow biofilms for evaluation of FlexCare and Triumph toothbrushes



CDFF = constant depth film fermenter; HA = hydroxyapatite.

Specimen Preparation

Saliva samples collected from 30 individuals in good oral health (age range, 18-40 years) were processed and stored at –20°C for use in inoculating the CDFF chambers. The CDFF chambers contained 75 hydroxyapatite (HA) disks, 2 mm in diameter, arranged in 15 pans (5 disks per pan) on which the biofilm was grown at a constant depth of 200 µm. The biofilm was allowed to develop for 8 days of growth under aerobic conditions at 37°C with 5% CO_2. Upon harvest from the CDFF, biofilms from selected HA disks were used in 1 run of the brushing experiment. Treatment order randomization for the

[b]Procter & Gamble Co; Cincinnati, OH.

biofilm-coated HA disks was performed by a selection matrix that allowed laboratory staff to remain blinded to the nature of treatments and outcomes. A pan containing disks was removed as needed and requisite disks selected with any remaining disks returned to the CDFF to prevent desiccation of the biofilms. Care was taken not to disturb the biofilm when removing the pans or manipulating the disks. Disks were then transferred to the typodont for testing by the brushing apparatus.

Brushing Experiments

Fully charged power toothbrushes were positioned with respect to the typodont tooth section according to each manufacturer's instructions. Separation between the bristles and the interproximally located HA disks was visually set at 2 mm to 3 mm as the active toothbrush was moved across the typodont. A pair of biofilm-coated HA disks was placed in interproximal recesses between representative mandibular molars, one on either side of the interproximal space flush with the surface of the tooth. In this location, the biofilm-coated HA disks represented plaque on the interproximal tooth surface. The exposure chamber was filled with 7 mL of phosphate-buffered saline (PBS) solution to mimic fluid levels at the dentition during a typical brushing. Treatment order was randomized.

The load force between the brushes and the teeth conformed to a value derived from conventional use of both powered toothbrushes. After each brushing (15 seconds for the 5-tooth typodont section), the fluid in the brushing chamber containing biofilm bacteria removed as a result of the power toothbrushes was completely extracted with a disposable curved syringe. The fluid was transferred to sterile 15-mL conical tubes. Paired disks containing remnant biofilms were aseptically transferred into 7-mL PBS solution, vortexed for 10 minutes, and probe-sonicated for 10 seconds to eliminate remaining bacteria not removed by fluid forces. Fluid representing bacteria eradicated by the power toothbrushes and that remaining on disks were both diluted 1:10 (1 mL of fluid to 9 mL of sterile PBS solution). Aliquots of this dilution were then plated on tryptic soy agar plates supplemented with 5% sheep's blood. Plates were incubated aerobically at 37°C for 24 hours in 5% CO_2 before bacterial colonies were enumerated.

This study consisted of a single run of the CDFF for a total of 8 paired replicates for each of the 3 treatment arms. Colony-forming units (CFUs) were recorded for each of the replicates and normalized to the volume of brushing fluid sampled (CFU/mL) to represent the amount of biofilm removed with that test.

Statistical Analysis

Triplicate viable count data were used to calculate mean CFU/mL for each replicate. The percentage of biofilm removal from the disk relative to total counts (sum of bacteria removed from disks as a result of treatment and bacteria remaining on disks) was determined. In the subsequent analysis of variance, percentage reduction was the dependent variable and the treatment group was the independent variable, with $P = .05$ defined as the level of significance. FlexCare was the active control compared with Triumph active and FlexCare inactive, using Dunnett's multiple comparison test.

Results

As expected, baseline pretreatment data showed no significant differences among treatment average counts ($P > .94$), so that all 3 treatments exhibited comparable initial conditions, about 10^7 CFU/mL for all samples.

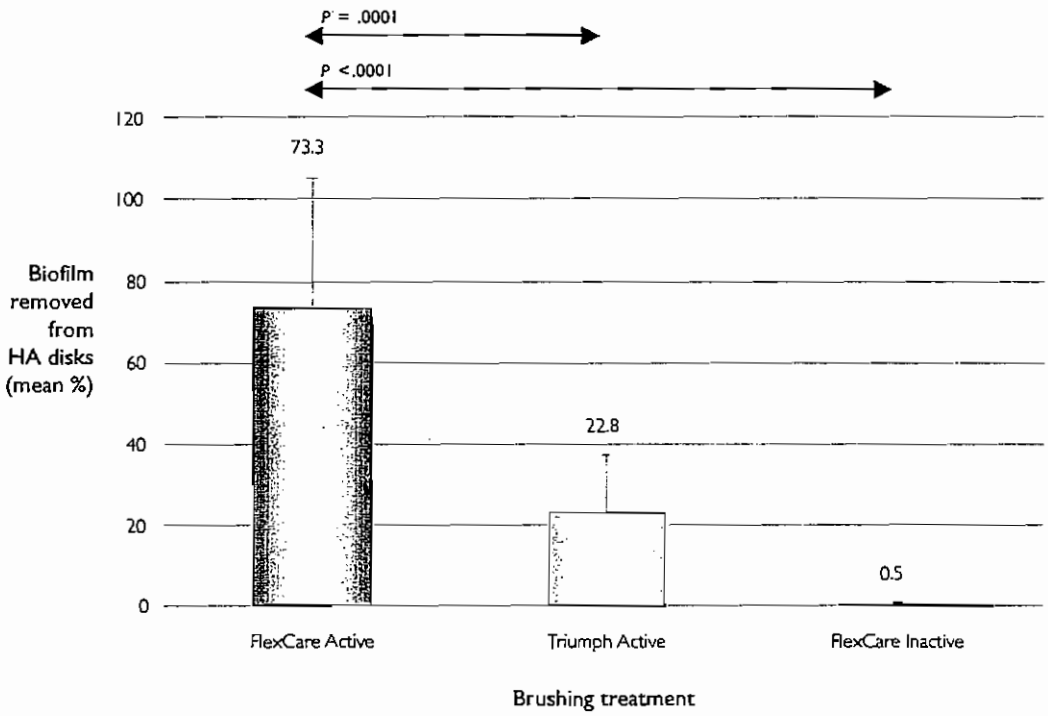
Figure 2 shows that the percentage of plaque biofilm from interproximal spaces in the typodont model was 73.3% for the active FlexCare, 22.8% for the active Triumph, and 0.5% for the inactive FlexCare. The percentage of interproximal plaque biofilm removal by the active FlexCare was significantly higher than both the inactive brush ($P < .0001$) and the active Triumph ($P = .0001$). Based on the percentage of biofilm bacteria removed, the efficacy of biofilm plaque removal by the active Sonicare FlexCare toothbrush was 3.2 times greater than the active Oral-B Triumph toothbrush.

Discussion

Dental plaque biofilm develops on hard surfaces, such as teeth in the oral cavity. Conventional toothbrushes that clean tooth surfaces remove dental plaque primarily in areas that are directly accessible to the bristles. However, accumulation of dental plaque also occurs in regions inaccessible to the mechanical effects of direct bristle contact. These areas include interproximal spaces, the sulcus, the gumline, and tooth pits and fissures.

In contrast to conventional toothbrush cleaning, the Sonicare toothbrush has been shown to remove biofilm bacteria beyond the reach of the bristles. Fluid forces generated by the rapid motion of the Sonicare brush head bristles are channeled into interproximal regions that the bristles cannot contact directly. The dynamic fluid motion removes plaque biofilm in these hard-to-reach areas.[9,11-13]

Figure 2—Mean percentage biofilm (in CFU/mL) removed from HA disks by active treatment with FlexCare and Triumph



CFU = colony-forming unit; HA = hydroxyapatite.

Data from these experiments are consistent with earlier findings, which revealed that fluid activity associated with the Sonicare toothbrush removed more biofilm in the interproximal space than a power toothbrush with rotating–oscillating motion.[12,13,18] Results from the present study demonstrate a 3-fold greater removal of interproximal biofilm bacteria with the new Sonicare FlexCare power toothbrush than with the Oral-B Triumph toothbrush. Interestingly, this 3-fold reduction pattern of interproximal plaque biofilm was also observed in previous studies comparing earlier Sonicare models (Sonicare Plus and Sonicare Elite) with Oral-B models.[12,13] This superior performance is probably due to the magnitude and the direction of the fluid motion generated by the Sonicare toothbrush. Fluid is actively propelled into interproximal areas between the teeth, rather than along the same side of the dentition as the bristles (such as the smooth facial or lingual surfaces of the teeth), as appears to occur with rotating–oscillating toothbrushes. In addition, the FlexCare toothbrush likely demonstrated a heightened velocity of fluid flow through the interproximal spaces, thereby increasing biofilm dislodgement in these hard-to-reach areas.

Another observation made was the increased generation of bubble activity by the Sonicare FlexCare toothbrush when compared with the Triumph toothbrush. Bubbles have a propensity to create localized fluid forces that act to displace biofilms from a substratum.[19-21] It is possible that the heightened bubble activity generated by the bristle movements of the Sonicare FlexCare toothbrush was more effective in channeling these localized fluid forces into the concealed niches of interproximal areas.

Conclusion

In summary, when comparing 2 active powered toothbrushes, hydrodynamic fluid forces generated by the Sonicare FlexCare induced a 3-fold greater reduction of interproximal plaque biofilm than Oral-B Triumph. The results of this in vitro study have demonstrated that the Sonicare FlexCare toothbrush removes a significantly higher percentage of plaque biofilm in interproximal areas than the Oral-B Triumph toothbrush.

Acknowledgment

This study was sponsored by a grant from Philips Oral Healthcare, Inc, Snoqualmie, WA.

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Exhibit H

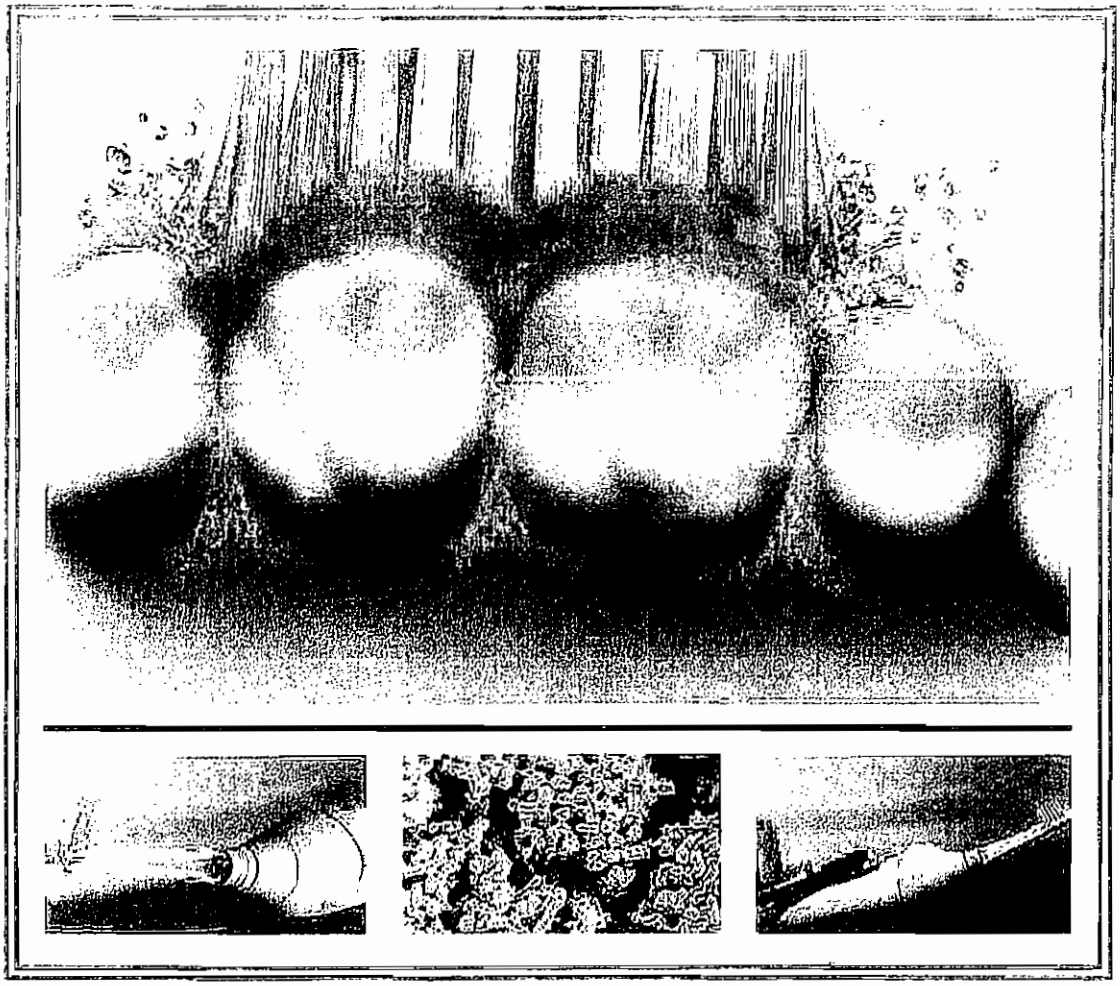
An MWC Publication
October 2004 / Vol. 25, No. 10 (Suppl 1)

A Supplement to

Compendium

of Continuing Education in Dentistry®

Review of Clinical Research on the IntelliClean System From Sonicare® and Crest



Supported by Philips Oral Healthcare, Inc, and The Procter & Gamble Company

Compendium
of Continuing Education in Dentistry®

A Realistic and Clinically Efficacious Way to Foster Patient Compliance with Home Oral Care Regimens

Throughout the course of routine practice, clinicians and hygienists encounter challenging patients who do not fully comply with the daily routines necessary to sustain sound oral health. They may not brush for the recommended full 2 minutes twice each day, or properly floss between their teeth and gums. In our efforts to promote the importance of correctly performing these tasks, we communicate the devastating and potentially painful consequences of unchecked food acids and gingivitis, as well as the documented link between oral bacteria and systemic disease.

If we've piqued their concern enough to warrant questions regarding appropriate products to use, we are then faced with guiding them through myriad toothbrushes, dentifrices, flosses, etc, to those best suited to their clinical needs, personal preferences, and, most importantly, personal habits. And that, for all dental professionals, becomes an additional challenge, because manufacturers have employed creative concepts to entice and intrigue the public into purchasing products that claim to make daily oral care easier, more comfortable, and even more enjoyable. Research-based recommendations to our patients are our obligation, but issues of compliance still loom.

To induce compliance, what we need to introduce to our patients is a product that (1) intrinsically encourages its regular and proper use; (2) "automates" compliance with accepted brushing regimens; and (3) achieves the clinically proven efficacy and benefits that we, as dental health care providers, want for our patients.

To this end, this supplement to *The Compendium of Continuing Education in Dentistry* is dedicated to empowering you with research-based support for the new IntelliClean System from Sonicare® and Crest®, a single product that achieves all of these objectives as proven through the extensive research documented on the following pages. The IntelliClean System is intuitively designed to combine proven Sonicare® technology with the efficacy of a specially formulated Crest® liquid toothpaste. As a result, you can be assured that your patients will demonstrate heightened oral care compliance, caused in part by their ability to personalize the brushing experience while still adhering to the recommended 2-minute brushing regimen. Overall, the research data presented in this supplement suggest that the IntelliClean System is a breakthrough innovation in oral care that can deliver meaningful results to your patients and keep them compliant with the home oral care regimens necessary for improved oral health.

Sincerely,

D. Walter Cohen

Dr. D. Walter Cohen
Dean-Emeritus, University of Pennsylvania, School of Dental Medicine
Chancellor-Emeritus, Drexel University College of Medicine
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The Compendium of Continuing Education in Dentistry

This supplement to *The Compendium* was supported by Philips Oral Healthcare, Inc, and The Procter & Gamble Company.

Review of Clinical Research on the IntelliClean System From Sonicare® and Crest

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A Novel Oral Hygiene System Through Integration of a Sonic Toothbrush and Liquid Toothpaste

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Abstract: ***A novel system for home oral hygiene, the IntelliClean System from Sonicare® and Crest® is an integrated sonic toothbrush and liquid-toothpaste dispensing system. New research has established the ability of this system to reduce plaque, especially in interproximal regions, and to reduce gingivitis. The unique capability for the user to reapply liquid toothpaste during brushing (ie, re-dose) allows for a greater reduction in bacteria in the sulcus and an enhanced in-use experience that leads to improved compliance with brushing instruction, specifically longer brushing times. Through in vitro and in vivo studies, the system and its constituents have been shown to be safe for daily use.***

Dental professionals recognize the importance of regular oral hygiene by their patients at home and understand the power of a simple regimen of brushing twice daily for 2 minutes with a fluoride toothpaste and flossing between teeth once a day. Both brushing and flossing require good technique for the patient to maintain or improve oral health, and, quite naturally, patient education and encouragement are routinely incorporated into office visits. The results are mixed, of course, depending on the patients, their ability, and their interest. Cleaning between teeth is especially problematic for many patients, including those who floss regularly but do not use proper technique.

There is still a clear need for products that offer improved interproximal cleaning. Philips Oral Healthcare, Inc, and The Procter & Gamble Company have jointly developed the new IntelliClean System from Sonicare®,[a] and Crest®,[b] to address this need (Figure 1). The IntelliClean System combines the proven sonic technology of the Sonicare® power toothbrush family with a liquid toothpaste specially formulated to work with the toothbrush's patented high-speed bristle motion. At the push of a button, the toothpaste is dispensed from a replaceable cartridge inside the toothbrush handle directly to the bristles (Figure 2), and the user can operate the toothpaste pump to dispense additional toothpaste on demand during brushing for targeted cleaning in particular areas. The toothbrush motion liquefies the toothpaste and, as reported elsewhere in this supplement, drives the cleaning ingredients between teeth and into the gingival sulcus.[1] Although the IntelliClean System is not intended to replace daily flossing, it can provide better cleaning between teeth for many patients, bringing them one step closer to the results of daily flossing.

The Sonicare® toothbrush within the IntelliClean System is built fundamentally on the same platform as the Sonicare® Elite®,[a] toothbrush, which

[a]Philips Oral Healthcare, Inc, Snoqualmie, WA 98065; 800-676-SONIC
[b]The Procter & Gamble Co, Cincinnati, OH 45202; 800-492-7378

was described by McInnes and Pace.[2] Central to both is the patented 260-Hz, side-to-side motion of the bristle tips,[3] which creates dynamic fluid activity in the mouth. According to in vitro studies conducted by Hope and Wilson[4] and Adams and colleagues,[5] such fluid activity can remove plaque from beyond the reach of the bristles significantly better than a rotational-oscillation power toothbrush. The IntelliClean System also incorporates the "double scallop" bristle trim profile of Elite®, so that the bristles fit the natural contour of teeth. The thin, oval head shape with broadly rounded edges allows for good accessibility to the back of the mouth while remaining gentle against soft tissue.

Dental professionals recognize the importance of regular oral hygiene by their patients at home and understand the power of a simple regimen of brushing twice daily for 2 minutes with a fluoride toothpaste and flossing between teeth once a day.

The Crest® IntelliClean liquid toothpaste[b] has a unique rheological profile optimized specifically for the IntelliClean System. Under the high shear conditions of pumping or brushing, it is thin enough to be readily dispensed by the pump, dispersed quickly in saliva, and transported between the teeth and into the sulcus under the action of the brush's high-speed bristle action; conventional toothpastes are not readily pumped and do not mix so easily in the mouth with the Sonicare® bristle motion. Under low shear conditions, the IntelliClean liquid toothpaste remains viscous enough to stand on the bristle tips. According to the manufacturer, the liquid toothpaste additionally has levels of foaming and flavor that consumers rate highly and that may be lacking in other toothpastes when used with a sonic toothbrush.

The IntelliClean liquid toothpaste is available in standard and whitening formulas. Both varieties contain sodium fluoride (1,100 ppm) as the active ingredient for anticaries efficacy and have been shown to be effective against caries using methods accepted by the US Food and Drug Administration (data on file, The Procter & Gamble Company). The whitening formula additionally contains sodium tripolyphosphate, which is well established as a whitening agent in toothpastes.[6,7]

Published clinical research also has established the anticalculus benefits of polymeric pyrophosphate adjuncts when included in toothpaste formulations.[8,9] Laboratory studies involving crystal growth inhibition and plaque biofilm calcification were conducted to confirm the anticalculus potential of the whitening liquid toothpaste. This methodological approach already has been shown to provide meaningful and predictive results relative to the proven in vivo performance of toothpaste containing anticalculus agents.[10,11] The whitening liquid toothpaste produced activity similar to formulations clinically proven for anticalcu-

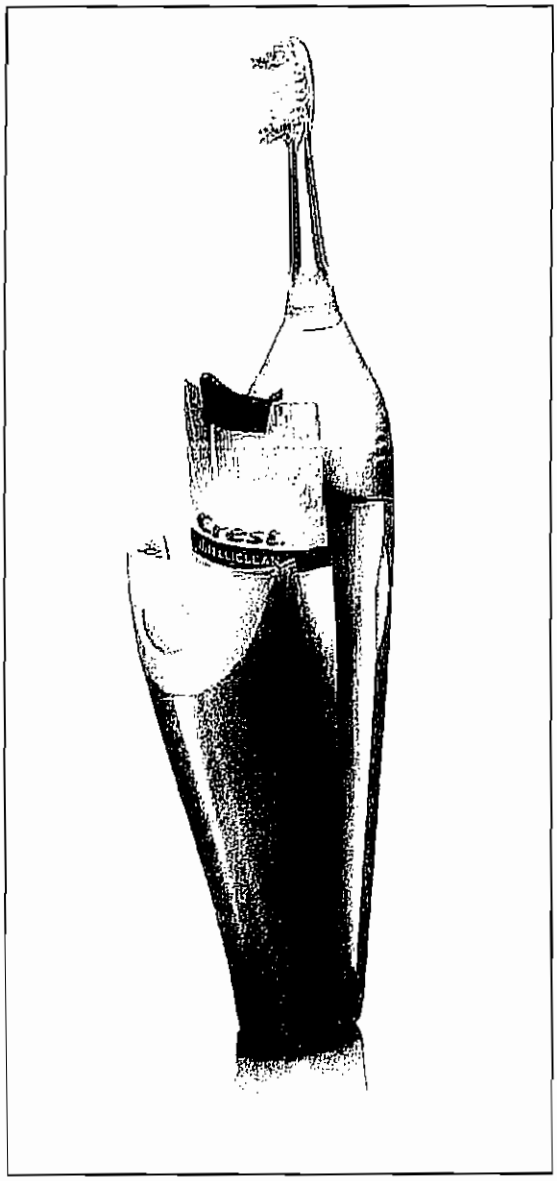

Figure 1—The IntelliClean System.

Gamble Company). These results support the anticalculus clinical activity of this new whitening liquid toothpaste.

The IntelliClean System has been through extensive safety testing. The liquid toothpastes all have been tested for gentleness on the oral hard and soft tissue using preclinical and clinical experiments to ensure that they satisfy safety reassurance assumptions. In evaluating hard tissue safety of the liquid toothpastes, preclinical evaluations of relative enamel and dentinal abrasivity were undertaken at independent testing facilities according to American Dental Association protocols.[12,13] In all instances, the liquid toothpastes exhibited levels of hard tissue abrasivity that were significantly less than reference controls. The formulations meet the international standard,[14] falling well below the upper limit of 250 and thus confirming their safety for daily use. Separately, the Sonicare® brush technology offers an excellent oral hard tissue safety profile that has been shown in vitro to be significantly gentler on dentin than other toothbrushes when used with the Crest® IntelliClean liquid toothpastes.[15]

Both brushing and flossing require good technique for the patient to maintain or improve oral health.

Clinical safety evaluations undertaken as part of the development of the liquid toothpaste formulations include more than 30 randomized controlled clinical studies where oral soft tissue tolerability was evaluated as either a primary or secondary objective. In a variety of designs involving short- and long-term exposure, the frequency and incidence of oral soft tissue irritation were comparable to negative controls (data on file, Philips Oral Healthcare, Inc, and The Procter & Gamble Company). Importantly, during typical home use, as in the clinical studies presented in this supplement[16-19] and in the pilot studies conducted during the system's development, there have been no more significant or serious adverse events reported that were attributable to the IntelliClean System than for the commercially available toothpastes and toothbrushes used as control products in these studies. In conclusion, in-use exposure to more than 500 subjects indicates the integrated power toothbrush/liquid toothpaste formulations to be clinically well tolerated.

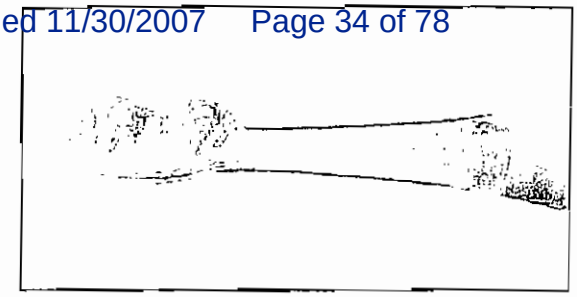

Figure 2—Liquid toothpaste is dispensed onto the bristles from a replaceable cartridge inside the handle.

The IntelliClean System's toothpaste dispensing system additionally has been shown to resist bacterial contamination. To investigate this potential hazard unique for an oral hygiene system such as this, 18 human subjects were recruited to use the system twice per day according to manufacturer's instructions for 4 weeks. After this exposure period, brush heads were sectioned at specific locations, placed into separate tubes containing a growth medium, and thoroughly vortexed to disperse the contents of the dispensing system in each section. Each section's solution was then pipetted onto three different types of agar plates using the drop streak method. Plates were incubated at 37°C for 2 days and then checked for the presence of bacteria. No bacteria were detected inside the toothpaste channel within the brush neck.

The clinical performance of this new integrated product is summarized within this supplement. Notably, the IntelliClean System offers cleaning performance in interproximal regions—and overall—that is superior to manual toothbrushing with conventional toothpaste, as described by Nunn and colleagues.[16] Rethman and coworkers report that a positive toothbrushing experience motivates patients to better comply with oral hygiene instruction, specifically longer brushing times.[17] Greater

Cleaning between teeth is especially problematic for many patients, including those who floss regularly.

plaque removal, and longer brushing times both likely play a role in the significant improvement in gingival health in subjects after 4 weeks of using the IntelliClean System, as observed by Barlow and colleagues.[18] The ability to dose additional toothpaste during brushing clearly translates into a greater effect in plaque bacteria control in the gingival sulcus as observed by Barlow and coworkers in a separate study.[1] Like other Sonicare® toothbrushes, the IntelliClean System is effective at reducing extrinsic stains, as confirmed in another study by Nunn and colleagues.[19] It has also been shown in vitro by Yuen and coworkers[15] to exhibit "beyond the bristles" cleaning and to be gentle on dentin, significantly more so than the Oral-B® ProfessionalCare 7000[c], a leading rotational oscillation toothbrush.

The IntelliClean System from Sonicare® and Crest® is the first integrated power toothbrush and toothpaste system. That in itself is noteworthy. For dental professionals and their patients, however, there are more important implications. Superior efficacy and greater compliance lead to improved oral hygiene for patients, including those less compliant with oral hygiene instruction. Better oral health outcomes will result from this breakthrough in home oral care.

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[c]Oral-B Laboratories, Boston, MA 02127; 800-446-7252

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Plaque Reduction Over Time of an Integrated Oral Hygiene System

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Abstract: ***This article compares the efficacy of a prototype integrated system (the IntelliClean System from Sonicare® and Crest®) in the reduction of supragingival plaque to that of a manual toothbrush and conventional toothpaste. The integrated system was compared to a manual toothbrush with conventional toothpaste in a randomized, single-blinded, parallel, 4-week, controlled clinical trial with 100 subjects randomized to each treatment group. There was a low dropout rate, with 89 subjects in the manual toothbrush group (11% loss to follow-up) and 93 subjects in the integrated system group (7% loss to follow-up) completing the study. The Turesky modification of the Quigley and Hein Plaque Index was used to assess full-mouth plaque scores for each subject. Prebrushing plaque scores were obtained at baseline and at 4 weeks after 14 to 20 hours of plaque accumulation. A survey also was conducted at the conclusion of the study to determine the attitude toward the two oral hygiene systems. The integrated system was found to significantly reduce overall and interproximal prebrushing plaque scores over 4 weeks, both by 8.6%, demonstrating statistically significant superiority in overall plaque reduction (P = .002) and interproximal plaque reduction (P < .001) compared to the manual toothbrush with conventional toothpaste, which showed no significant reduction in either overall plaque or interproximal plaque. This study demonstrates that the IntelliClean System from Sonicare® and Crest® is superior to a manual toothbrush with conventional toothpaste in reducing overall plaque and interproximal plaque over time.***

Oral microorganisms accumulating on the surface of the teeth in the form of dental plaque may give rise to caries, calculus, or inflammatory changes in adjacent tissue. Chronic gingivitis and periodontitis are considered to be diseases in the oral cavity that result from dental plaque.[1] Associations between periodontal disease and systemic illness involving the cardiovascular system have been proposed.[2] Thus, the removal of dental plaque has been and remains the mainstay of preventive dentistry.[3]

Regular and proper use of a manual toothbrush is effective in removing dental plaque. However, studies have shown that power toothbrushes have improved efficacy over manual toothbrushes.[4-8] Conventional power toothbrushes rely primarily on contact of the bristles with the teeth, as do manual toothbrushes, but they increase the efficacy by automating the back-and-forth or up-and-down motion of the bristles and sometimes by rotating the bristles. In certain power toothbrushes, notably the Sonicare® toothbrush[a], the brush's high-frequency motion not only cleans by direct bristle–tooth contact but also creates dynamic fluid pressure and shear forces that have been shown in laboratory studies to disrupt and disperse bacterial plaque beyond the reach of the bristles.[9-11]

In numerous controlled clinical trials, various versions of the Sonicare® sonic toothbrush were shown to be effective and safe in dental plaque removal overall and, specifically, in interproximal areas in a wide range of

[a]Philips Oral Healthcare, Inc, Snoqualmie, WA 98065; 800-676-SONIC

quency motion has now been incorporated into a new product. The IntelliClean System from Sonicare® and Crest®[b] is an integrated sonic-power toothbrush and liquid-toothpaste dispensing system that, at the touch of a button, delivers the liquid toothpaste directly into the brush head. The purpose of the clinical trial was to compare the efficacy of a prototype IntelliClean System with IntelliClean liquid toothpaste to the efficacy of a manual toothbrush with conventional toothpaste in reducing supragingival plaque over a 4-week period of regular brushing.

Materials and Methods

Overview

The clinical study compared the efficacy of a prototype integrated system in the reduction of supragingival plaque to that of a manual toothbrush and conventional toothpaste. For inclusion in this study, participants had to have at least 20 natural teeth without crowns, a minimum overall mean Turesky plaque score[20] of 1.8, no urgent need for extensive dental treatment, no systemic disease that might interfere with oral health, absence of generalized severe gingivitis, and no severe periodontal disease (ie, no periodontal pockets of 7 mm or greater).

The design of this study was a parallel, single-blinded, randomized, controlled clinical trial with the examiner blinded to assigned treatment groups. Before visit 1, the examiner was calibrated for repeatability using the Turesky modification of the Quigley and Hein

Associations between periodontal disease and systemic illness involving the cardiovascular system have been proposed.

Plaque Index[20] on a population equivalent to those selected for the current study.

All participants were required to read, sign, and date the informed consent form approved by the Institutional Review Board before starting the study. Participants also were instructed to call the telephone number provided on the informed consent form in case of any suspected adverse effects. Participants were examined as

[b]The Procter & Gamble Co, Cincinnati, OH 45202; 800-492-7378

Treatment Groups

Control group (manual toothbrush with conventional toothpaste): Subjects randomized to the control group were provided with an Oral-B® Indicator® 35 manual toothbrush[c] and Crest® Cavity Protection Cool Mint Gel toothpaste[b] with active ingredient sodium fluoride (0.243% weight). They were provided with detailed brushing instructions and also were told to brush their teeth for 2 minutes twice a day throughout the course of the study. No

The removal of dental plaque has been and remains the mainstay of preventive dentistry.

additional oral hygiene aids, such as floss, mouth rinses, etc, were to be used throughout the course of the study. In addition to brushing twice a day, subjects also were instructed not to brush for 14 to 20 hours before each visit to allow for plaque accumulation when plaque scoring would be conducted.

Test group (prototype integrated system): Subjects randomized to the test group were provided with a prototype of the IntelliClean System with IntelliClean liquid toothpaste. They were supplied a kit containing one complete plastic power brush and one charger plus four toothpaste cartridges to be used over the course of the study. The toothbrush device in the integrated system, manufactured by Philips Oral Healthcare, Inc, is built on the company's Sonicare® brushing platform. The Sonicare® toothbrush in the integrated system incorporates high-frequency bristle motion with a 2-minute timer and an audible indication every 30 seconds during brushing to signal the user to move the brush from quadrant to quadrant for a more even distribution of brushing time. A label that designated the device as an "Investigational Product" and included a 24-hour telephone number was placed on the toothbrush component of the integrated system for questions and to report any problems. The directions for use of the integrated system and the informed consent form also clearly stated that the IntelliClean

[c]Oral-B Laboratories, Boston, MA 02127; 800-446-7252

liquid toothpaste was a prototype and provided a 24-hour telephone number for questions and/or concerns.

The integrated system additionally incorporates a push-button pump to allow the user to dispense toothpaste from a toothpaste cartridge, which is integrated into the device, into the toothbrush bristles on demand, before and during brushing. The toothpaste is a sodium fluoride liquid toothpaste manufactured by The Procter & Gamble Company in accordance with good manufacturing practices and federal regulations concerning fluoride-based anticaries toothpaste. The prototype toothpaste was packaged within 15-mL volume, soft-side cartridges that fit into the prototype device. Each toothpaste cartridge was labeled with nonremovable clinical test labels listing a reference to usage directions, the active ingredient, and its concentration (sodium fluoride, 0.243% weight), as well as a 24-hour telephone number for any questions or concerns.

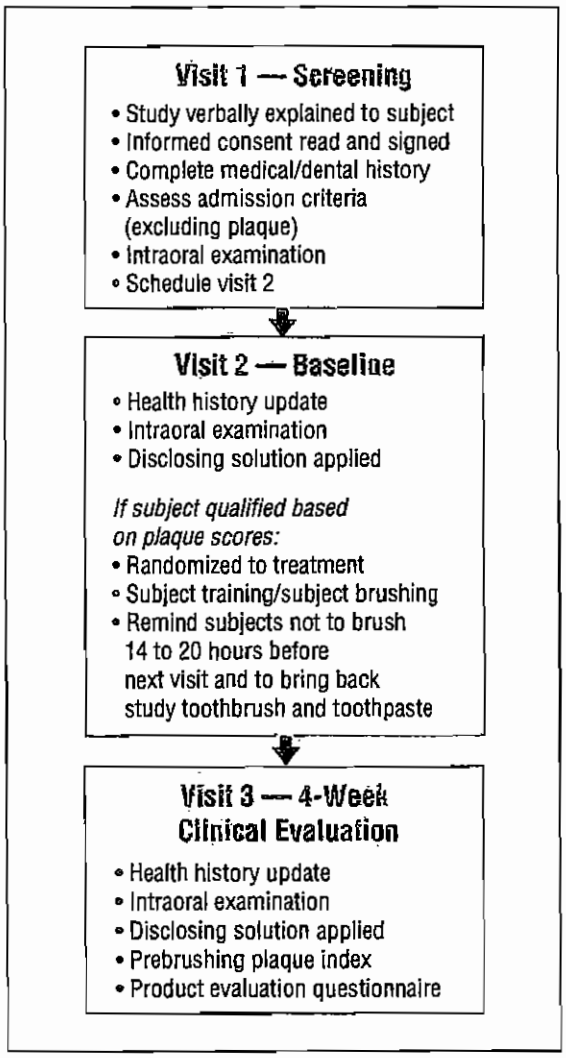

Figure 1—Flowchart of study.

Study Population

Two hundred people met the criteria for admission into the study and were enrolled and randomized to either the manual toothbrush with conventional toothpaste or the integrated system. There were 182 participants who completed the study (89 in the manual toothbrush group and 93 in the integrated system group), with 11 lost to follow-up for the manual group and 7 lost to follow-up for the integrated system group. Participants were dropped from the study if they failed to allow time for plaque accumulation, experienced power brush failure, returned to the study center with the wrong brush, or did not return for follow-up.

Statistical Analysis

Plaque reduction over 4 weeks: Summary statistics were computed for prebrushing plaque scores at baseline and at 4 weeks for each treatment group. Both overall plaque scores and interproximal plaque scores were computed as well as the change in the prebrushing plaque score from baseline to 4 weeks for both overall and interproximal plaque. Percent reduction in plaque also was calculated for each group. Baseline differences between treatment groups were tested using 2-sample *t* tests. Paired *t* tests were used to determine if there was a statistically significant reduction in prebrushing plaque scores from baseline to 4 weeks for each treatment group.

To investigate the clinical differences in plaque removal between the manual toothbrush with conventional toothpaste and the integrated system, the percentage of sites with plaque scores greater than 1 were evaluated to determine if the prebrushing plaque scores were improved at 4 weeks. The mean percentages of sites with initial prebrusing plaque scores greater than 1 that also showed improvement were calculated for all sites (interproximal sites, posterior sites, anterior sites, posterior interproximal sites, and anterior interproximal sites) for each subject in the study. The mean percentages of improved sites by treatment group and location were then calculated from subject-level mean percentages. Comparisons between groups were conducted using 2-sample *t* tests.

To further investigate differences in prebrushing plaque reduction over 4 weeks between the 2 treatment groups, analysis of covariance (ANCOVA) was used with the corresponding baseline prebrushing plaque score

Table 1—Summary Statistics for Prebrushing Plaque Scores by Treatment Group

Enamel(a)	n	Mean (Median)	SD	Range	P-value*
Overall Prebrushing (Baseline)					
Manual Toothbrush w/toothpaste	89	2.44 (2.38)	0.36	(1.85, 3.63)	
IntelliClean System	93	2.44 (2.41)	0.42	(1.80, 3.39)	.978
Overall Prebrushing (4 Weeks)					
Manual Toothbrush w/toothpaste	89	2.44 (2.42)	0.42	(0.57 3.44)	
IntelliClean System	93	2.22 (2.19)	0.60	(0.58, 3.66)	.005
Overall Prebrushing Reduction					
Manual Toothbrush w/toothpaste	89	0.000 (–0.04)	0.41	(–0.74, 1.98)	
IntelliClean System	93	0.216 (0.16)	0.51	(–0.81, 2.14)	.002
Interproximal Prebrushing (Baseline)					
Manual Toothbrush w/toothpaste	89	2.57 (2.55)	0.33	(1.91, 3.69)	
IntelliClean System	93	2.56 (2.52)	0.39	(1.83, 3.59)	.808
Interproximal Prebrushing (4 Weeks)					
Manual Toothbrush w/toothpaste	89	2.59 (2.59)	0.38	(0.79, 3.43)	
IntelliClean System	93	2.33 (2.31)	0.58	(0.62, 3.66)	< .001
Interproximal Prebrushing Reduction					
Manual Toothbrush w/toothpaste	89	–0.017 (–0.08)	0.38	(–0.68, 1.92)	
IntelliClean System	93	0.225 (0.16)	0.50	(–0.81, 2.10)	< .001

*P values are based on 2-sample t tests.
SD = standard deviation.

included as a covariate. Adjusted means and 95% confidence intervals (CIs) from ANCOVA for both overall plaque and interproximal plaque also were computed.

Product Evaluation Questionnaire

At the completion of the study, participants in both groups were asked questions regarding their attitude toward their assigned toothbrush. Frequencies of participant responses for both the integrated system group and the manual toothbrush group were computed and compared using the chi-square test of independence.

Results

Of the 182 participants who completed the study, 61% (111 of 182) were women. The distribution of race/ethnicity was 70.9% (129 of 182) Caucasian, 16.5% (30 of 182) African American, 7.1% (13 of 182) Hispanic, and 5.5% (10 of 182) other. The age range of subjects completing the study was 18 to 68 years, and the mean age was 37 (standard deviation = 13.17; median = 38 years). No statistically significant difference in gender, race, or age by treatment group was detected.

With respect to intraexaminer reliability, statistical testing of repeated plaque scores showed that the simple kappa statistic, an indication of agreement among examinations, was 0.916 and a weighted kappa statistic was 0.964. A kappa statistic of 0.75 and above represents excellent agreement.[21]

Summary statistics for prebrushing plaque scores were calculated for each treatment group at baseline and at 4 weeks. In addition, summary statistics for reduction in prebrushing plaque scores over 4 weeks as well as percent reduction in prebrushing plaque scores over 4 weeks were calculated for each treatment group. Comparisons between groups were conducted using a 2-sample *t* test. Summary statistics by group are presented in Table 1. No difference in either overall plaque at baseline or interproximal plaque at baseline was detected between the manual toothbrush and the integrated system groups. Based on paired testing, the integrated system group demonstrated statistically significant reduction in both overall prebrushing plaque ($P < .001$) and interproximal prebrushing plaque ($P < .001$) over 4 weeks, whereas no significant reduction in either overall plaque ($P = .997$) or interproximal plaque ($P = .668$) was noted for the manual toothbrush group. In addition, both overall plaque reduction ($P = .002$) and interproximal plaque reduction ($P < .001$) were significantly greater in the integrated system group compared to the manual toothbrush group.

To investigate clinical differences in plaque reduction between the manual toothbrush with conventional toothpaste and the integrated

system, the mean percentage of sites with initial prebrushing plaque scores greater than 1 that also showed improvement were calculated and compared using 2-sample *t* tests. The integrated system group exhibited a significantly greater percentage of sites with improvement in prebrushing plaque after 4 weeks ($P < .005$), with the most pronounced differences noted for anterior sites ($P < .001$) and anterior interproximal sites ($P < .001$) (Figure 2).

To further investigate differences in plaque reduction over time, ANCOVA was conducted with and adjusted for baseline prebrushing plaque scores. The integrated system group had an adjusted-mean overall plaque reduction of 0.216 (95% CI: 0.124 to 0.308), whereas the manual toothbrush group had an adjusted-mean overall plaque reduction of 0 (95% CI: –0.094 to 0.093). In other words, the integrated system demonstrated a significant reduction in plaque over time whereas the manual toothbrush with conventional dentifrice showed no reduction in plaque over time. Similarly, the integrated system group had an adjusted-mean interproximal reduction of 0.227 (95% CI: 0.140 to 0.315), whereas the manual toothbrush group showed an adjusted-mean change in interproximal plaque of –0.020 (95% CI: –0.109 to 0.070), ie, no significant change in prebrushing interproximal plaque over 4 weeks. Differences between treatment groups in the adjusted-mean reductions for overall plaque and interproximal plaque were both statistically significant ($P = .001$ and $P < .001$, respectively).

There were four oral adverse events (AEs) reported during this study, and all were judged by the principal investigator to be mild in severity. The AEs included an ulceration for one subject in the manual toothbrush group, judged possibly related to treatment, and tooth sensitivity and gum irritation for one subject in the integrated system group, judged probably related to treatment. The other AE was judged doubtfully related to treatment, and the one serious AE reported was judged definitely not related to treatment.

Questionnaire Response

There were 188 subjects (98 subjects in the integrated system group and 90 subjects in the manual toothbrush group) who responded to the questionnaire. Table 2 shows the distribution of responses by treatment group. Comparisons were made using a chi-square test of independence. Significantly more participants in the integrated system group (87.8%) reported that the study brushing system was better than their usual method of brushing. This compares to only 14.4% in the manual toothbrush group reporting that their study brush was better than their usual method. A significantly greater percentage of participants in the inte-

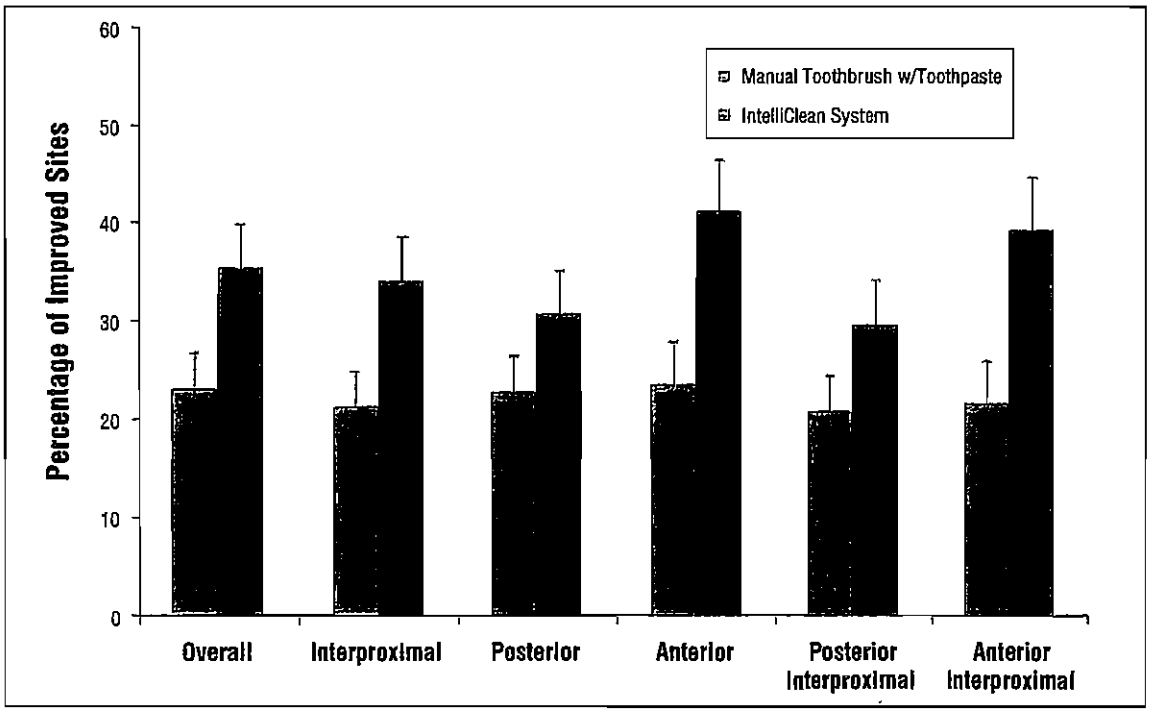

Figure 2—Percentage of improved sites with baseline prebrushing plaque scores > 1.

Table 2—Distribution of Responses to Questionnaire Items by Treatment Group

	Percentage		
	Manual (n = 90)	IntelliClean (n = 98)	P value
How would you rate the study brushing system compared to the toothbrush and toothpaste you use most often?			
Better	14.4	87.8	
Same	63.3	5.1	
Worse	22.2	7.1	< .001
How likely are you to replace your current toothbrush with the study brush?			
Very likely	4.4	45.9	
Somewhat likely	23.3	27.6	
Not sure	30.0	7.1	
Somewhat unlikely	18.9	4.1	
Very unlikely	23.3	15.3	< .001
"I feel excited and motivated to brush with the study brushing system."			
Strongly agree	10.0	50.0	
Somewhat agree	33.3	22.4	
No opinion	37.8	17.3	
Somewhat disagree	11.1	3.1	
Strongly disagree	7.8	7.1	< .001
"My overall oral health has improved due to brushing with the study brushing system."			
Strongly agree	6.7	42.9	
Somewhat agree	24.4	24.5	
No opinion	42.2	24.5	
Somewhat disagree	15.6	4.1	
Strongly disagree	11.1	4.1	< .001
"I would recommend the study brushing system to others."			
Strongly agree	23.3	58.2	
Somewhat agree	21.1	22.4	
No opinion	33.3	8.2	
Somewhat disagree	15.6	5.1	
Strongly disagree	6.7	6.1	< .001

grated system group reported that they were likely to replace their current toothbrush with the study toothbrush (ie, the integrated system), with 73.5% reporting that they were either "somewhat likely" or "very likely" to do so. In the manual toothbrush group, only 27.7% reported a likelihood of replacing their usual toothbrush with the study brush (ie, the manual toothbrush with conventional toothpaste). Significantly more participants in the integrated system group were "excited and motivated" about the study brushing system compared to the manual group (72.4% in the integrated system group vs 43.3% in the manual toothbrush group); more participants in the integrated system group felt that their "overall oral health" had improved compared to participants in the manual toothbrush group (67.4% vs 31.1%); and more participants in the integrated system group would "recommend the study brushing system to others" compared to the manual toothbrush group (80.6% vs 44.4%).

Discussion

This study demonstrated that the use of the IntelliClean System with IntelliClean liquid toothpaste over a 4-week period is highly effective in reducing plaque, exhibiting a significant reduction in prebrushing plaque scores, whereas the manual toothbrush with conventional toothpaste did not significantly reduce prebrushing plaque scores over 4 weeks. The safety of the integrated system is further substantiated by the low number of AEs possibly or probably related to treatment for the test group, similar to the number observed for the control group. The results from this study agree with the safety testing on the IntelliClean liquid toothpaste reported elsewhere in this supplement[22] and in previously published studies demonstrating the effectiveness of Sonicare® toothbrush technology in reducing plaque over time.[13,19]

Improvement in plaque levels over time also was evaluated by tabulating the percentage of sites with prebrushing plaque scores greater

than 1 that showed improvement over 4 weeks. The percentage of sites showing improvement in plaque over time was assessed for all sites, interproximal sites, posterior sites, posterior interproximal sites, anterior sites, and anterior interproximal sites. The integrated system was found to be significantly better than the manual toothbrush with conventional toothpaste for all of these areas. In particular, the integrated system was found to demonstrate the most pronounced superiority in reducing plaque over time for anterior sites and anterior interproximal sites compared to the manual toothbrush with conventional toothpaste.

In addition to the objective measures of plaque reduction, subject questionnaires revealed that the integrated system was well-liked by study subjects, with almost 90% saying that the new system was better than what they had been using before the study. In addition, almost 70% of subjects in the integrated system group indicated that their overall oral health had been improved by using the integrated system. One can reasonably speculate that an oral hygiene system that is liked by patients and that delivers to the patient a perceived improvement in oral health is an oral hygiene system that will be used regularly, and this may be another benefit of the integrated system.

Conclusion

In this randomized parallel study, the prototype integrated IntelliClean System from Sonicare® and Crest® was found to be superior to a manual toothbrush with conventional toothpaste in the reduction of plaque over time. This study also strengthens previous claims about the effectiveness of interproximal plaque removal with the Sonicare® technology incorporated into the integrated system. In addition to the objective measures of plaque reduction over time, subject questionnaire responses demonstrated that the integrated system is well-liked by subjects, receiving higher approval ratings than the manual toothbrush and conventional toothpaste.

Acknowledgment

The authors thank Ashley Barlow of The Procter & Gamble Company for his assistance.

Disclosure

This study was conducted at Hill Top Research, Inc, West Palm Beach, Florida, and was sponsored by Philips Oral Healthcare, Inc.

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Effect of a Novel Integrated Power Toothbrush and Toothpaste Oral Hygiene System on Gingivitis

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Abstract: *The purpose of this article is to compare the gingivitis reduction efficacy relative to baseline of an integrated power toothbrush/toothpaste dispensing system prototype, the IntelliClean System from Sonicare® and Crest®. This was a randomized, controlled, parallel-group, examiner-blind study that examined the gingivitis reduction efficacy of a novel integrated system compared to a positive control consisting of manual toothbrushing coupled with daily flossing over a 4-week period. Mean change from baseline for gingival index (GI) and bleeding scores were tested using paired t tests for each treatment group, separately. Between-group comparisons were made with respect to change from baseline using analysis of covariance. Baseline values were used as the covariate. All tests were 2-sided with a 0.05 level of significance. A total of 66 subjects (61 women and 5 men) completed the study. The subjects ranged in age from 20 to 64 years with an overall mean age of 39.4 years. Baseline GI and bleeding scores were not statistically significantly different (P > .2) between the experimental integrated system group and the positive-control group. Both treatment regimen groups demonstrated highly statistically significant reductions in GI and bleeding scores vs baseline (P < .0001) at weeks 2 and 4. After 4 weeks, there was a 28% mean reduction in GI for the experimental group and a 23% mean reduction for the positive-control group. Similarly, there was a 28% mean reduction in bleeding for the experimental integrated system group and a 23% reduction for the positive-control group. However, no statistically significant treatment difference was found between the 2 groups (P > .5) for either measure at week 2 or week 4. This study demonstrated the efficacy of the IntelliClean System from Sonicare® and Crest® in significantly reducing gingivitis and bleeding relative to baseline after 4 weeks of use according to the manufacturer's instructions.*

It is widely recognized that the removal or prevention of plaque accumulation on the tooth surface, either by mechanical or chemotherapeutic means, will prevent gingivitis.[1] Plaque growth left unchecked at the gingival margin rapidly leads to a proliferation of pathogenic bacteria and their associated toxic metabolic by-products.[2] The resulting inflammatory response manifests as red and/or swollen gums and, in most cases, prompts spontaneous gingival bleeding.

Dental professionals have long sought an effective means of removing dental plaque, thus preventing or reducing gingivitis. Adjunctive hygiene measures, such as flossing, also are promoted to target interproximal surfaces where brushing alone can have less impact.[3,4] If undertaken frequently, and

using the right technique and duration, a combination of manual toothbrushing and daily flossing will deliver excellent oral health.[5] Unfortunately, research has indicated that patients find adherence to such regimens problematic. Not only is the frequency and duration of toothbrushing hard to maintain, but compliance with a daily regimen of flossing also is low (2% to 20%).[5,6]

The introduction of power toothbrushes has offered a more effective means of removing plaque than manual toothbrushing. A review of the published literature reveals multiple examples of studies where power brushes have outperformed their manual counterparts.[7-12] Through a combination of electronic user-guidance aids (such as built-in timers and dual-speed control switches) and greater acceptance, power toothbrushes represent a good option for dental professionals seeking better oral hygiene for their patients. Unlike many power toothbrushes, the Sonicare® toothbrush[a] was designed to deliver not only physical bristle contact with the teeth to remove plaque but also a fluid dynamic action derived from the bristle motion that has been shown in vitro to disrupt plaque biofilms.[13,14] Numerous studies, employing a wide range of designs, clinical end points, and study populations, also have demonstrated the ability of this brush to deliver clinically meaningful results.[7,15-17]

It is widely recognized that the removal or prevention of plaque accumulation on the tooth surface, either by mechanical or chemotherapeutic means, will prevent gingivitis.

Building on the benefits of the Sonicare® technology, the IntelliClean System from Sonicare®,[a] and Crest®,[b] combines a power toothbrush and toothpaste dispensing system into one device. Using a specially formulated liquid dentifrice designed to work in combination with the bristle action, this system offers a novel approach to addressing the issues of oral hygiene performance and patient acceptance.

The primary aim of this study was to evaluate the magnitude of effect, relative to baseline, of this novel integrated brush/paste system vs a positive-control oral hygiene regimen (manual toothbrushing with daily flossing). In considering the most appropriate design parameters for this research, the authors considered the existing guidelines prepared by the American Dental Association (ADA) for toothbrush performance with respect to plaque removal and gingivitis-reduction efficacy. As such, Löe-Silness,[1] a recognized gingival index (GI), was employed and a minimum of 25 subjects (68 randomized) were assigned to use either treatment for a period of 28 days. Proof of efficacy was evaluated based on achieving at least a 15% reduction in gingivitis relative to baseline.

Materials and Methods

Study Procedures

This was a randomized, controlled, examiner-blind, parallel-group study that examined the gingivitis reduction efficacy of a novel integrated power toothbrush/toothpaste dispensing system vs a positive control of manual toothbrushing with daily flossing over a 4-week period. The protocol, including consent form, was approved by an independent ethics committee. All subjects participated voluntarily in the study and were required to read, understand, and sign an informed consent form before being enrolled. Reduction in gingivitis after 4 weeks of treatment relative to baseline was considered the primary efficacy parameter, with levels of gingivitis evaluated using the Löe-Silness GI at baseline and at 2 and 4 weeks. Approximately 80 subjects aged 18 to 65 years with a minimum of 16 gradable teeth were screened. Subjects were considered eligible for participation based on having a moderate level of gingivitis (a minimum of 20 bleeding sites at baseline), their ability to comply with the protocol, and freedom from obvious oral disease conditions such as rampant caries and periodontitis. Subjects also were excluded if they were pregnant.

Participants refrained from all oral hygiene procedures for a period of approximately 12 hours before any evaluation of gingivitis. Subjects were appointed between 7:30 AM and 12:30 PM to facilitate compliance with the study requirements and were queried regarding compliance with instructions before each study visit. Eligible participants reporting to the clinical facility at baseline were randomly assigned to one of the following two treatment groups according to a computer-generated randomiza-

[a]Philips Oral Healthcare, Inc, Snoqualmie, WA 98065; 800-676-SONIC
[b]The Procter & Gamble Co, Cincinnati, OH 45202; 800-492-7378

Table 1—Löe-Silness Gingival Index	
0	Absence of inflammation
1	Mild inflammation. Slight change in color and texture. No BOP.
2	Moderate inflammation. Moderate glazing, redness, edema, and hypertrophy. There is BOP.
3	Severe inflammation. There is a marked redness and hypertrophy, a tendency toward spontaneous bleeding, and ulceration.

BOP = bleeding on probing.

tion plan prepared in advance of the study:

1. Prototype Integrated Oral Hygiene System (an experimental rechargeable power toothbrush with integrated toothpaste-dispensing system using a novel sodium-fluoride liquid toothpaste). At the baseline visit, study personnel familiarized the subjects in this treatment group with the system's operation, toothpaste dispensing, and the correct brushing technique. Subjects were instructed to brush their teeth for 2 minutes twice a day for the next 4 weeks.

2. Oral-B® Indicator® Toothbrush[c] (brush head size 35) with Crest® Decay Prevention Toothpaste[b] and Oral-B Waxed Floss (mint flavor).[c] A qualified oral hygienist trained the subjects in this treatment group on the correct toothbrushing and flossing technique. Subjects were instructed to brush their teeth twice per day using the toothbrush and toothpaste assigned to them in combination with daily whole-mouth flossing.

Participants were recalled after 2 days and then weekly to check compliance with the study procedures and to receive further oral hygiene instructions relevant to their assigned treatment. They were examined by a single examiner using the Löe-Silness GI at baseline and at weeks 2 and 4[1,18] (Table 1).

Probing, as part of the examination process, involved inserting a periodontal probe approximately 1 mm to 2 mm at the gingival margin and angling the probe at a 45° angle under moderate axial pressure, sweeping interproximally along the buccal and lingual aspects of the tooth. Gingivitis was measured on six surfaces per tooth (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, and distolingual) on all natural teeth except the third molars, which were excluded. In all, there were a possible 168 observations per subject (assuming a maximum of 28 natural teeth). Mean GI scores were derived for each subject by summing the subject's individual GI scores and dividing by the number of sites graded for that subject. In addition, the number of bleeding sites for a subject was computed by summing all sites scored as 2 or 3.

[c]Oral-B Laboratories, Boston, MA 02127; 800-446-7252

Statistical Methods

Comparisons to baseline were of primary interest. For each subject at each visit, whole-mouth average GI and total number of bleeding sites scores were calculated. Change from baseline values were obtained by subtracting baseline values from postbaseline values at weeks 2 and 4. Mean changes from baseline for GI and bleeding scores were tested using paired *t* tests for each treatment group, separately. Between-group comparisons were made with respect to change from baseline using an analysis of covariance. Baseline values were used as the covariate. Separate models were fitted for the Löe-Silness GI score and for the number of gingival bleeding sites. All tests were 2-sided with a 0.05 level of significance.

Results

Sixty-eight subjects were enrolled in the study. Of these, one subject was withdrawn before completing the baseline examination because of an inability to comply with the protocol requirements. Another subject voluntarily withdrew from the study at the 2-week visit, citing personal reasons. A total of 66 subjects, comprising 61 women and 5 men, completed the study. The subjects ranged in age from 20 to 64 years with an overall mean age of 39.4 years. There were no statistically significant ($P > .8$) differences between the 2 treatment groups

Table 2—Demographics					
		Age		Gender	
	n	Mean ± SD	P value	Percent Female	P value
IntelliClean System	33	39.7 ± 9.4	.8364	90.9	≥ .9
Manual brushing + daily flossing	33	39.2 ± 11.9		93.9	

SD = standard deviation.

Table 3—Reduction of Gingival Inflammation						
		Baseline (SD)	Change from Baseline* (SD)	Percent GI Reduction†	Change from Baseline* (SD)	Percent GI Reduction†
IntelliClean System	33	0.54 ± 0.24	−0.19 ± 0.16	35.2	−0.15 ± 0.16	27.8
Manual brushing + daily flossing	33	0.48 ± 0.16	−0.18 ± 0.14	37.5	−0.11 ± 0.16	22.9

SD = standard deviation; GI = gingival index.
*Changes from baseline at weeks 2 and 4 are highly statistically significant ($P < .001$).
†Percent GI reduction = 100% x (baseline score − 2-week/4-week score)/baseline score, calculated from group means.

with respect to these demographic characteristics (Table 2).

Baseline GI scores were not significantly different between the experimental and the positive-control groups, with mean (standard deviation [SD]) GI scores of 0.54 (0.24) and 0.48 (0.16), respectively (Table 3). Both treatment regimens demonstrated highly statistically significant reductions in GI vs baseline ($P < .001$) at weeks 2 and 4. At the 2-week evaluations, the mean percent GI reductions were 35% for the experimental integrated system group and 38% for the manual brushing with daily flossing group. After 4 weeks, there was a 28% mean GI reduction for the experimental integrated system and a 23% mean reduction for manual brushing with daily flossing. The experimental integrated system had a directionally greater GI reduction at week 4. However, this difference was not statistically significant.

Baseline bleeding site scores were 39.2 ± 16.5 and 35.0 ± 11.5 for the experimental integrated system and the manual brushing with flossing regimen groups, respectively. There were no statistically significant differences between the two groups ($P > .2$). Both treatment regimens demonstrated highly statistically significant reductions in the number of bleeding sites vs baseline ($P < .001$) (Table 4).

At the 2-week evaluations, the mean percent reductions in the number of bleeding sites were between 34% and 37% for both treatment groups. After 4 weeks, there was a 28% mean reduction for the experimental integrated system and a 23% mean reduction for manual brushing with daily flossing. Both mean reductions were statistically significant ($P < .001$). However, no statistically significant ($P > .6$) difference was found between the two treatment groups at either week 2 or 4.

Figure 1 shows the distribution of bleeding site reduction by treatment at week 4. In the experimental integrated system group, 33% of the participants experienced greater than a 15-site reduction in the occurrence of bleeding vs 27% in the manual brushing with daily flossing group. Overall improvement in bleeding and gingival inflammation was observed in more than 82% of subjects after 4 weeks of treatment for the experimental integrated system group and 64% for the manual brushing with daily flossing group.

There were 18 adverse events (AEs) reported during the course of this study, of which 4 were considered either possibly or probably related to treatment. One subject from each treatment group experienced two AEs. The nature of these AEs ranged from swollen palate and in-mouth numbness sensation in the experimental integrated system group, to sore and/or hypersensitive gums in the manual brushing with daily flossing group. All the AEs were considered mild in nature and were fully resolved before study completion.

Discussion

The outcomes from this study clearly demonstrate a significant gingivitis-reduction efficacy for the integrated power toothbrush/

Table 4—Reduction in Bleeding Sites						
		Baseline (SD)	Change from Baseline* (SD)	Percent Bleeding Site Reduction†	Change from Baseline* (SD)	Percent Bleeding Site Reduction†
IntelliClean System	33	39.2 ± 16.5	−13.5 ± 11.0	34.4	−10.9 ± 11.8	27.8
Manual brushing + daily flossing	33	35.0 ± 11.5	−12.8 ± 9.9	36.6	−7.9 ± 11.3	22.6

*Changes from baseline at weeks 2 and 4 are highly statistically significant ($P < .001$).
†Percent bleeding site reduction = 100% x (baseline score − 2-week/4-week score)/baseline score, calculated from group means.

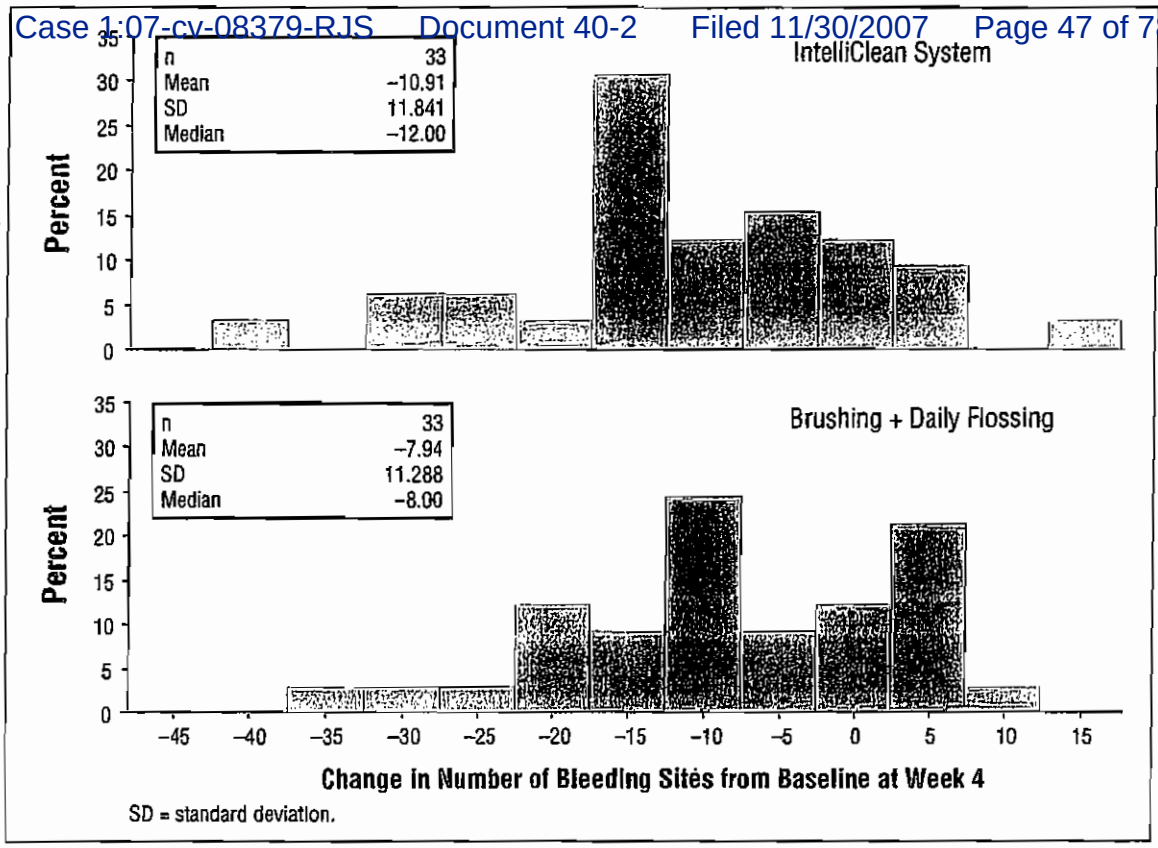

Figure 1—Distribution of the change in the number of bleeding sites for each subject at week 4.

toothpaste dispensing system. The results replicate findings from other research that also have shown a gingival health benefit from using Sonicare® toothbrushes.[7,15,19] Importantly, the study design offered the advantage of considering the outcomes in relation to a positive-control treatment. Given the comparable levels of both GI and bleeding site reductions observed among those subjects assigned to the experimental and the positive-control groups, the inferences drawn from these results can be considered meaningful.

The design used in this study was derived from the current ADA guidelines that are in place to ensure a minimum standard of performance for any toothbrush technology with respect to gingivitis efficacy. Research published elsewhere in this supplement demonstrates the ability of the IntelliClean System to significantly reduce prebrushing plaque levels over a 4-week period vs a negative control.[20] The results from this study show an average reduction of approximately 28% for the IntelliClean System after 4 weeks of use relative to baseline, nearly twice the current ADA criteria of 15%. Overall, more than 76% of the subjects using the experimental system achieved greater than a 15% reduction in gingivitis.

Change-from-baseline studies, where the absolute magnitude of effect is the primary efficacy variable, require careful interpretation. They are liable to confounding effects, such as Hawthorne effects or natural drift, on behalf of the examiner. Regarding these results, such factors can be discounted given the distribution of the bleeding sites (Figure 1) and similar GI responses at 4 weeks within both the experimental and positive-control groups. A proportion of the study participants showed no improvement or a continued worsening of gingivitis over the course of the study. Such observations clearly point to the influence of other experimental factors. Here, the 2-week results may help to provide some insight.

Both treatment groups demonstrated a decrease in response (albeit not statistically significant) after 4 weeks of treatment vs 2 weeks. A marginal 7% reduction in benefit was observed at 4 weeks for subjects using the experimental integrated system vs a more significant 14% to 15% reduction for subjects using manual brushing with floss. Given the level of motivational instruction throughout the study in both treatment groups, the result could be described as unexpected. As already pointed out, willingness to comply with a daily flossing

regimen is difficult for many individuals, even in a clinical study setting.[5,6] It is certainly possible that the lack of response in some subjects and the directional increase in disease parameters from week 2 to week 4 is the product of poor compliance. Importantly, the change between visits was lower for the integrated system, and the integrated system delivered a smaller number of nonresponders. In comparison to the positive-control group, this phenomenon owes much to the ability of the experimental system to promote acceptance and, therefore, compliance by the user. Rethman and colleagues have demonstrated significant compliance benefits for the IntelliClean System vs another power toothbrush.[21]

Conclusion

This randomized, controlled, clinical study demonstrated a significant reduction in gingivitis and bleeding relative to baseline after 2 and 4 weeks of using the IntelliClean System from Sonicare® and Crest®. The magnitude of the benefit was comparable to the benefit of using manual brushing with daily flossing.

Disclosure

The Procter & Gamble Company supported this research.

Acknowledgments

The authors acknowledge Clare McAlinden of The Procter & Gamble Company, Dr. Douglas Dudgeon of Philips Oral Healthcare, Inc, and the staff of Hill Top Research, Inc, Europe, for their contributions to this research.

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Pharmacodynamic and Pharmacokinetic Effects in Gingival Crevicular Fluid From Re-dosing During Brushing

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Abstract: *The IntelliClean System from Sonicare® and Crest® combines a rechargeable sonic power toothbrush and a novel liquid toothpaste into one integrated system, providing the opportunity to re-dose with toothpaste during the brushing cycle. The purpose of this study was to investigate cleaning effects from in-mouth re-dosing with toothpaste during the brushing cycle vs conventional bolus dosing. This was a randomized, examiner-blind, six-period, crossover clinical study. Eighteen adult subjects used an experimental integrated system employing either a re-dosing regimen (2 doses at the start of brushing with 1 additional in-mouth dose during the last 30 seconds of brushing [2+1]) or a conventional regimen (2 doses at the start of brushing only [2+0]). Gingival crevicular fluid (GCF) was sampled at the final brushing quadrant from a preselected site in the gingival sulcus using filter strips at baseline and at 4, 15, and 120 minutes postbrushing. Mean change from baseline in the concentrations of total facultative anaerobes (TFAs) and gram-negative anaerobes (GNAs) in the GCF at 120 minutes posttreatment were modeled separately using general linear mixed models. Area under the curve of surfactant (sodium dodecyl sulfate [SDS]) in GCF over 2 hours postbrushing was calculated and modeled using an analysis of variance model. All hypotheses were tested 2-sided at the 5% significance level. Relative to the conventional regimen, the re-dosing (2+1) regimen produced a significantly greater reduction in $\log_{10}$ (TFA colony-forming units [CFU]/μL GCF) after brushing, 0.99 ± 0.12 vs 0.65 ± 0.12 (mean change ± standard error), and a significantly greater reduction in $\log_{10}$ (GNA CFU/μL GCF) after brushing, 0.75 ± 0.14 vs 0.45 ± 0.14. The re-dosing regimen led to significantly more SDS in GCF relative to the conventional regimen over the 2-hour time period. Re-dosing of liquid toothpaste during the brushing cycle with the IntelliClean System leads to a significantly increased cleaning effect, as defined by a reduced bacterial count in GCF, and significantly higher levels of surfactant in the GCF up to 2 hours after the brushing event.*

Mechanical and/or chemotherapeutic cleaning of the oral cavity to remove or inhibit plaque growth remains the most effective means of promoting good oral health. Oral hygiene products continue to evolve rapidly by employing the latest advances in engineering, electronics, and chemistry to develop more effective cleaning technologies. Of those products available directly to the consumer, power toothbrushes have been recognized as making a positive contribution toward improved daily plaque control. Studies report improved plaque removal efficacy vs manual brushes as well as significant improvements in gingival and periodontal health.[1-4] Rechargeable power toothbrushes employing sonic technology are among the most innovative, delivering improved cleaning performance and an enhanced user experience.[5-7]

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Similarly, toothpastes have improved as a result of advances in chemical formulation and the identification of novel ingredients. Stable fluoridated toothpastes containing either high-performance cleaning ingredients, substantive antibacterial agents, or combinations of the two are more readily formulated and can offer multiple oral health benefits.[8,9] A new system, the IntelliClean System from Sonicare®,[a] and Crest®,[b], has combined novel toothbrush and toothpaste technologies in an integrated oral hygiene product. The product uses a low-viscosity sodium-fluoride liquid toothpaste that has been specially developed to maximize both the cleaning performance of a sonic toothbrush and the in-use consumer experience. The stain, gingivitis, and plaque benefits of this system have been evaluated.[10-12] As well as enhanced cleaning, the system provides the opportunity to re-dose with toothpaste without interrupting the brushing cycle. Given the proven hydrodynamic action of sonic brush technology[7] and low-viscosity toothpaste, this unique feature may offer additional cleaning benefits.

Gingival crevicular fluid (GCF) is generally recognized as a key source of biomaterial suitable for studying the environmental factors associated with periodontal disease.[13,14] In clinically healthy individuals, GCF is a serum transudate, which can be readily collected from the sulcus after its passage through the junctional epithelium. As such, it contains most of the elements that are present in serum, but as a transudate into the gingival microenvironment it also is likely to contain plaque-derived microbes as well as related bacterial and host inflammatory response factors.[15] Quantitative and qualitative assessments of the GCF potentially can provide useful information about an individual's oral health status.[16] In certain situations, these evaluations may be particularly valuable in establishing cleaning or antibacterial performance of oral hygiene products.

Sodium dodecyl sulfate (SDS) is commonly used in personal cleansing and oral hygiene products, such as toothpaste. As a surfactant, it adds both esthetic and cleaning attributes to the formulation. Its chemical properties also may bestow limited bactericidal action, given the propensity of surfactants to break down phospholipid membranes.

The aim of this study was to determine the cleaning benefits from in-mouth re-dosing using a prototype integrated system representing the final and optimized brush design and toothpaste formulation.

Materials and Methods

Study Procedures

This was a randomized, single-center, examiner-blind, crossover clinical study. Eighteen adults (9 women and 9 men) with a mean age of 40 years were recruited. The study was limited to healthy individuals with gingival/periodontal pocket depths of 1 mm to 3 mm. All subjects gave written informed consent and agreed not to receive a dental prophylaxis or use any other dental product during the phase of active treatment. Subjects also were required not to use antibiotics during the study or within 2 weeks before the start of the study. At their initial visit, all subjects received a periodontal examination, including the identification of 3 gingival sites in the posterior upper quadrants that gave a crevicular fluid sample exceeding 25 Periotron®,[c] units. Typically, mesiobuccal or mesiolingual sites were chosen and recorded for future use during the study. Pocket depth and bleeding on probing status were recorded for each GCF sampling site (Figure 1).

Subjects used the prototype integrated toothbrush/toothpaste system once during each treatment period under supervision according to their assigned usage/dosing instructions. Otherwise, subjects were supplied with Crest® Cavity Protection toothpaste[b] and Sonicare® Advance toothbrushes[a] to be used for the duration of the study.

Subjects received instructions to brush each of the 4 dental quadrants for 30 seconds. Half of the subjects brushed in the right-to-left order as follows: upper right (Q1), lower right (Q4), lower left (Q3), upper left (Q2) (Figure 2); the other half brushed in the left-to-right

[a]Philips Oral Healthcare, Inc, Snoqualmie, WA 98065; 800-676-SONIC
[b]The Procter & Gamble Co, Cincinnati, OH 45202; 800-492-7378
[c]Oraflow, Inc, Plainview, NY 11803; 631-669-8954

Figure 1—Sampling of gingival crevicular fluid.

Regimen Sequence	Treatment Period 1	2	3	4	5	6
1	A	B	B	A	A	B
2	B	A	A	B	B	A
3	A	A	B	B	B	A
4	B	B	A	A	A	B

"A" and "B" represent the brushing regimens.

order as follows: upper left (Q2), lower left (Q3), lower right (Q4), upper right (Q1) (Figure 3).

After brushing, all subjects rinsed for 15 seconds with 30 mL of water. The treatment regimens employed a total of 2 minutes brushing time but differed with respect to the timing for the introduction of SDS-containing toothpaste into the mouth and the amount of SDS-containing toothpaste on the brush head, as follows:

Re-dose regimen (2+1): 2 pumps (~0.50 g toothpaste) delivered into the brush head to start brushing the upper quadrant (t = 0 seconds), 1 pump (~0.25 g toothpaste) delivered into the brush head to start brushing opposite the upper quadrant (t = 90 seconds). Re-dosing was reserved for the last 30 seconds of brushing, when the foam and body qualities of toothpaste are generally compromised from dilution effects.

Bolus-only regimen (2+0): 2 pumps (~0.50 g toothpaste) delivered into the brush head to start brushing the upper quadrant (t = 0 seconds).

Subjects were randomly assigned to one of the regimen sequences shown in Table 1 in a block size of 4 based on the subject's order of entry at the first day of treatment.

At the start of each treatment period, subjects had a baseline GCF sample taken from preidentified pharmacodynamic and pharmacokinetic sites. Subjects were blinded as to the location of these sites before study initiation. Subjects remained at the clinic for their 4- and 15-minute pharmacokinetic site GCF samplings and then returned to the clinic for pharmacokinetic and pharmacodynamic site samples 120 minutes after brushing. Subjects were not permitted to eat, drink, chew gum, or smoke between samplings.

Pharmacodynamic Procedures

1. Four Periotron® 8000 series instruments were calibrated before the start of the study according to the manufacturer's instructions. GCF samples were collected at the designated times by placing paper strips (PerioPaper®) at the entrance to the gingival sulcus for 30 seconds to absorb the fluid present.

2. GCF samples were collected at baseline from the upper quadrant (depending on the brushing sequence, the upper-left or the upper-right quadrant where brushing ended). Sampling sites were predetermined based on screening Periotron® values. A GCF sample was collected from the same sites used for baseline collection 120 minutes ± 5 minutes from the time the treatment was administered.

3. Periotron® units of the collected GCF volume were determined immediately after collection using the Periotron® 8000 series instruments. A calibration curve provided direct translation of Periotron® unit values to volumes that were reported in µL. The GCF volumes were used to obtain the final concentrations of bacteria expressed as colony-forming units

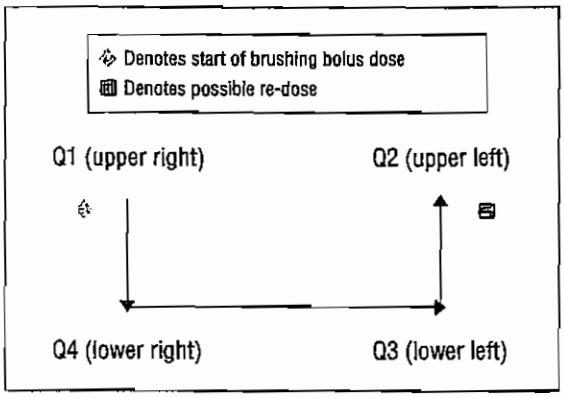


Figure 2—Brushing direction for brushing regimen A.

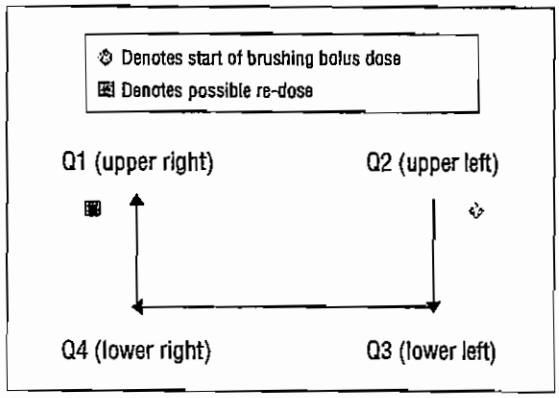


Figure 3—Brushing direction for brushing regimen B.

(CFU)/µL GCF.

4. Strips were cut with scissors to remove the orange plastic portion before placement into labeled sample vials containing 1 µL of Liquid Dental Transport (DTF)[d], caps closed, and then stored on ice before microbial processing. All pharmacodynamic processing was done within 2 hours of sample collection.

5. Appropriate cleaning and sterilization procedures were undertaken in between each sampling event.

6. To ensure mixing of the substrate before analysis, the Liquid Dental Transport was vortexed for 30 seconds at high speed before plating the sample. A neat sample (10^{-3}) and 1:10 (10^{-4}) and 1:100 (10^{-5}) dilutions of the neat sample were plated on Enriched Tryptic Soy Agar (ETSA)[d] for total facultative anaerobes (TFAs) and on Enriched Tryptic Soy Agar with nalidixic acid and vancomycin (ETSA-NV)[d] for gram-negative anaerobes (GNAs). All dilutions were prepared in sterile physiological saline. A spiral plater (Autoplater™ 4000[e]) was used for all platings.

7. Plates were incubated in an anaerobic chamber (AALC 3-DOOR[f]) at 37°C for 48 hours. Colonies were then enumerated using an automatic colony counter (QCount™[e]), and the counts were reported separately for the three dilutions as CFU/mL.

Oral hygiene products continue to evolve rapidly by employing the latest advances in engineering, electronics, and chemistry to develop more effective cleaning technologies.

Pharmacokinetic Procedures

1. Periotron® calibration, GCF sample collection, and quantification were performed as described for the pharmacodynamic procedures.

2. Strips were cut with scissors to remove the orange plastic portion before placement into a specified well of a 96-round, deep-well plate. Plate specification included subject identification, treatment period, time point, and whether the sample was collected from the upper-left or upper-right quadrant of the mouth. Plates containing the samples were stored frozen at –70°C until the time of analysis. Plates were removed from the freezer and allowed to reach room temperature before analysis.

3. Water (0.9 mL) was added to each well, followed by 0.1 mL of an internal standard solution containing a known mass of stable isotope labeled SDS (d_{25}).

Power toothbrushes have been recognized as making a positive contribution toward improved daily plaque control.

4. The plate was sealed with a cap mat and, to ensure mixing of the substrate before analysis, vortexed for 5 minutes before liquid chromatography tandem mass spectrometry analysis. An aliquot of the sample was injected onto an Xterra High Performance Liquid Chromatography column[g] using isocratic conditions. The column effluent was introduced into a triple quadrupole mass spectrometer (API 3000[h]) under turbo ion-spray conditions in the negative-ion–selected reaction monitoring mode. Transitions consisting of m/z 265 → 97 and m/z 290 → 98 were continuously monitored for SDS and d_{25}-SDS, respectively.

5. Calibration standards were prepared by spiking 1 µL of human plasma matrix containing a known mass of SDS onto PerioPaper® strips over the expected concentration range of the unknown samples. These standards were analyzed as described above. Samples with SDS concentrations exceeding the upper limit of the normal calibration range were further diluted with internal standard and reanalyzed.

6. A calibration curve was constructed by plotting peak area ratios of SDS/d_{25}-SDS vs the mass of SDS in each calibration standard. The mass of SDS contained in the unknown samples was then interpolated from the calibration curve. The mass of SDS in each unknown sample was then divided by the volume of GCF collected onto its respective strip to obtain the SDS concentration (ng SDS/µL GCF).

[d]Anaerobe Systems, Morgan Hill, CA 95037; 408-782-7557
[e]Spiral Biotech, Norwood, MA 02062; 800-554-1620
[f]COY Laboratory Products, Inc, Grass Lake, MI 49240; 734-475-2200
[g]Waters Corporation, Milford, MA 01757; 800-252-4752
[h]Applied Biosystems, Foster City, CA 94404; 800-327-3002

Table 2—Analysis of Covariance for Average Total Facultative and Gram-negative Anaerobes (TFA and GNA)

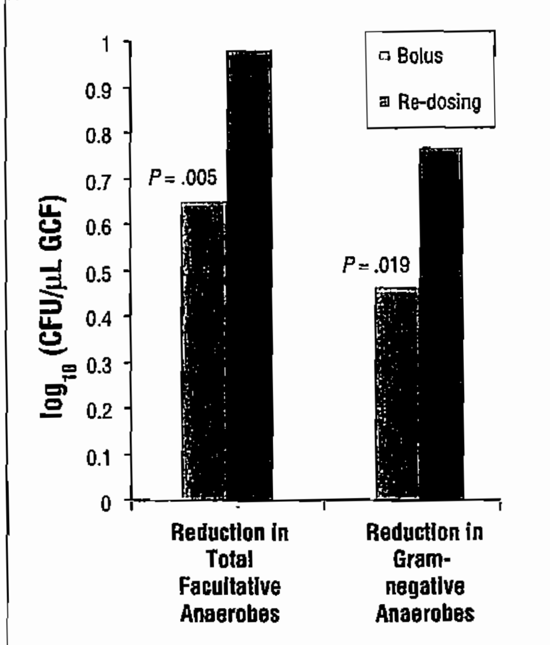
Regimens	Adjusted Mean Change	Adjusted Mean Final	Regimen Difference	Two-sided P value
$\log_{10}$ (TFA CFU/μL GCF)				
2+1 regimen	−0.99 (0.12)	8.06 (0.12)	−0.34	.005
2+0 regimen	−0.65 (0.12)	8.40 (0.12)		
$\log_{10}$ (GNA CFU/μL GCF)				
2+1 regimen	−0.75 (0.14)	7.09 (0.14)	−0.30	.019
2+0 regimen	−0.45 (0.14)	7.38 (0.14)		

CFU = colony-forming units; GCF = gingival crevicular fluid.

Statistical Methods

For the pharmacodynamic measurements, the base-10 logarithm function was applied to the concentrations of GNA CFU/μL GCF and TFA CFU/μL GCF data before statistical analysis. For the pharmacokinetic measurement, the area under the SDS concentration curve (AUC) was calculated using the trapezoid rule for each subject. The SDS AUC was the primary measure of surfactant delivery to GCF. The analysis was performed on the natural logarithm scale of the original data. The adjusted means were transformed back to the original scale for the purposes of reporting.

The mean change from baseline in the number of GNA CFU/μL GCF and TFA CFU/μL GCF and SDS AUC were modeled separately using general linear mixed models. Each model included treatment and period as fixed class variables. Subject was included as a random class variable with compound symmetric within-subject correlation structure. The models of mean change from baseline bacteria concentration levels also included the respective baseline CFU/μL GCF ($\log_{10}$ scale) as a continuous covariate. These general mixed models were used to compare regimens at the 5% significance level.



CFU = colony-forming units; GCF = gingival crevicular fluid.

Figure 4—Reduction in total facultative and gram-negative anaerobic bacteria 120 minutes posttreatment.

Results

Study Population

All 18 subjects who were randomly assigned to 1 of the 4 regimen sequences completed all study visits. Subjects used each of the two treatment regimens three times during the course of the study. Subject sampling sites ranged from 2 mm to 3 mm probing depth, and 1 of 36 sample sites displayed bleeding when pocket depth was measured at the screening visit.

Pharmacodynamic Results

Before brushing, subjects had an average of 9.05 $\log_{10}$ TFA CFU/μL GCF and 7.84 $\log_{10}$ GNA CFU/μL GCF. After 2 hours postbrushing, the mean TFA reduction compared to baseline was significantly greater for the 2+1 regimen than for the 2+0 regimen (0.99 vs 0.65 $\log_{10}$ CFU/μL GCF, $P = .005$). There was also a significantly greater mean reduction of GNAs in GCF for the 2+1 regimen compared to the 2+0 regimen (0.75 vs 0.45 $\log_{10}$ CFU/μL GCF; $P = .019$) (Table 2 and Figure 4).

Pharmacokinetic Results

The mean SDS concentration in GCF was statistically significantly ($P < .002$) higher for the 2+1 regimen relative to the 2+0 regimen at each of the 4-, 15-, and 120-minute time points. Over the 2-hour postbrushing period, the SDS AUC was statistically significantly ($P < .0001$) greater for the 2+1 re-dosing regimen than for the 2+0 bolus-only regimen (29.5 vs 19.2 μg x min/μL) (Table 3 and Figure 5).

Table 3—Analysis of Variance for the Area Under the SDS Concentration Curve (4 to 120 Minutes) in Gingival Crevicular Fluid (µg SDS x min/µL GCF)

Regimens	Adjusted Mean	Adjusted Mean Ratio	Two-Sided P Value
2+1 regimen	29.5	1.54	< .0001
2+0 regimen	19.2		

SDS = sodium dodecyl sulfate.

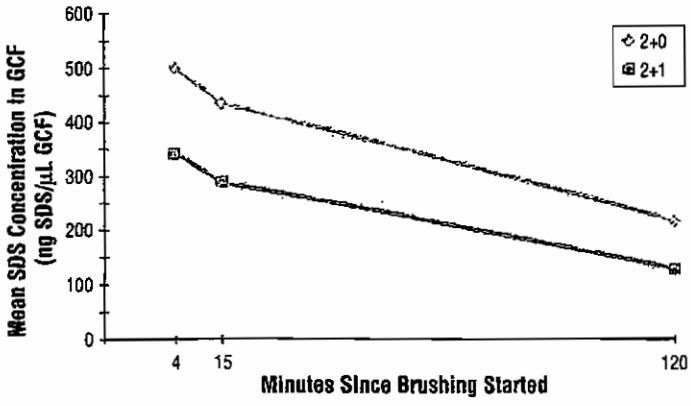
Discussion

The results of this study demonstrated the pharmacodynamic and pharmacokinetic benefits of re-dosing with toothpaste during the brushing cycle. A direct comparison of brushing cycles with and without an additional dose of liquid toothpaste indicated a significant reduction in TFAs and GNAs 2 hours after brushing had ceased. Re-dosing delivered approximately a log reduction in TFAs, a 52% greater effect than dosing only at the beginning of the brushing cycle. Differences for GNAs were similar, with a 66% greater log reduction in bacterial load in the GCF for the re-dosing vs regular regimen. The role of bacteria, specifically GNA classes, in the formation of plaque and subsequent initiation of gingivitis is well documented.[17-19] The ability of any oral hygiene regimen to positively affect the microbial flora within the sulcus is likely to aid the maintenance of healthy gingival tissues. The clinical relevance of such reductions remains to be established, although randomized clinical trials have already demonstrated antiplaque and antigingivitis effects for this integrated oral hygiene system.[10,11]

Similarly, the pharmacokinetic effects observed indicate the advantage of re-dosing to raise the amount of cleaning ingredients delivered into the gingival sulcus, thus prolonging the surfactant's activity in the oral cavity longer than with a bolus-only dose of toothpaste at the start of brushing. Over the 2-hour postbrushing period, the mean concentration of surfactant (SDS) in the GCF was 54% higher when an additional dose of toothpaste was dispensed during the brushing cycle compared to a bolus-only dose at the start of brushing. Importantly, the pharmacokinetic outcomes appear to be consistent with the pharmacodynamic results in supporting the overall cleaning benefits that can be observed in the GCF through re-dosing during the brushing cycle. From a pharmacokinetic perspective, there are clearly opportunities to explore the use of integrated antibacterial formulations and their impact on these evaluation parameters as a result of re-dosing.

The benefits of re-dosing during the brushing cycle are not yet fully characterized, and further experiments are required to fully understand the relative impact it may have vs the conventional toothbrush/toothpaste regimen. Research is ongoing to characterize the whole-mouth pharmacokinetic and pharmacodynamic profiles resulting from re-dosing if the actual quantity of product dispensed during the brushing cycle remains constant, ie, 3+0 vs 2+1. It is hypothesized that, by improving the distribution of the product within the mouth, the product's efficacy is less likely to suffer the dilution effects associated with bolus dosing. Supervised brushing to control brushing time and patterns was implemented to minimize individual habit influences and the impact, if any, of the subjects' awareness of sampling-site locations.

This research also focused on single-use effects, and it is clearly of interest to explore



SDS = sodium dodecyl sulfate; GCF = gingival crevicular fluid.

Figure 5—Mean sodium dodecyl sulfate concentration in gingival crevicular fluid over time.

the integrated system on cleaning and these evaluation parameters over time. Research reported elsewhere in this supplement indicates higher levels of compliance with the integrated system vs a separate toothbrush plus toothpaste over a 6-week period.[20] The result of that study indicated that user acceptance was higher with the integrated system, and it may be speculated that re-dosing plays an important role in this outcome by enhancing the usage experience.

Conclusion

Re-dosing with liquid toothpaste during the brushing cycle using an integrated sonic power toothbrush/low-viscosity liquid toothpaste leads to a significantly increased cleaning effect, defined as reduced bacteria count in GCF, vs bolus dosing at the start of brushing. Furthermore, re-dosing delivers significantly higher levels of surfactant to the GCF up to 2 hours after the brushing event vs bolus dosing at the beginning of the brushing cycle.

Disclosure

The Procter & Gamble Company supported this research.

Acknowledgments

The authors acknowledge Susan Fiedler and Phyllis Hoke of The Procter & Gamble Company for their contributions to this research.

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Brushing Compliance with a Novel Integrated Power Toothbrush and Toothpaste Oral Hygiene System

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Abstract: ***Patient motivation can be an important factor in successful compliance with an oral hygiene program. However, it also can present the most difficulty with such compliance. For example, some conditions, such as gingivitis, may seem nonthreatening, making adherence to recommended regimens especially difficult to attain. A new power toothbrush technology with an integrated toothpaste system has been developed that increases a patient's ability and willingness to adopt recommended regimens. This article reviews this novel technology and reports on a study comparing it to a nonintegrated power toothbrush and regular toothpaste. The features of the novel toothbrush technology also are explained in the context of patient concordance vs patient compliance.***

The impact of poor compliance to the self-care programs recommended by oral health care providers has been well documented.[1-4] In patients with chronic illnesses, such as periodontitis, a lack of improvement in plaque levels, inflammation, and/or bleeding have been directly correlated with the patient's lack of adherence to prescribed treatment regimens.[5] Furthermore, caries incidence rates have been shown to be adversely affected by the lack of compliance to recommended oral care routines.[6]

One of the key challenges of dental disease is the patient's perception that the condition is nonthreatening and, as such, the health risks involved are insignificant. This phenomenon is even more problematic in conditions such as gingivitis, where the health implications often are poorly understood by the patient. Of course, acute gum disease and its progression to a more destructive periodontal condition are directly linked to effective longitudinal plaque control.[7-9] Therefore, maintaining adequate plaque control between dental visits, irrelevant of the patient's health status, is a key aim of any dental professional. Of the treatment options available to the dentist/hygienist, devices that employ mechanical means to remove and prevent accumulation of plaque biofilm are regarded as the most effective.

When good technique, sufficient duration, and regular frequency of use are employed, toothbrushing has been shown to promote good oral health.[10-12] Brushing also can be complemented by adjunctive mechanical methods, such as flossing, interdental brushes, and toothpicks, to target areas where toothbrushes are less effective. The enhanced oral health benefits of these techniques in combination with toothbrushing are well documented in the literature.[13-15] In fact, an oral hygiene regimen involving regular toothbrushing and daily flossing is still regarded as the preferred approach to optimal oral health. However, it is clear that the success of these approaches is a function of patient instruction, technique, and overall motivation. Unfortunately, the process of brushing the teeth, let alone flossing them regularly, is an experience that most

Table 1—Demographic and Baseline Summary (by Treatment Group)

	IntelliClean System	Sonicare Elite Brush and Dispenser
Total Number of Subjects	169	175
Age: Number (Percent)		
18–24	13 (7.7%)	12 (6.9%)
25–34	22 (13.0%)	22 (12.6%)
35–45	75 (44.4%)	77 (44.0%)
46–55	59 (34.9%)	64 (36.6%)
Gender*: Number (Percent)		
Men	61 (36.1%)	57 (32.6%)
Women	108 (63.9%)	118 (67.4%)
Screener Brushing Time (Ordinal Data)†: Number (Percent)		
Up to 30 seconds	15 (8.9%)	15 (8.6%)
31 to 60 seconds	58 (34.3%)	51 (29.1%)
1 to 2 minutes	63 (37.3%)	69 (39.4%)
2 to 3 minutes	19 (11.2%)	27 (15%)
3+ minutes	14 (8.3%)	13 (8.3%)
Screener Brushing Time: Median (Range)		
Time (seconds)	90 (10–780)	90 (15–900)

*The Fisher exact test revealed no differences between groups. †The Wilcoxon signed-rank test showed no difference between groups.

people do not enjoy.[11] As a result, compliance with recommended brushing procedures generally is poor and, thus, the positive impact on oral health status is minimized. An additional inhibitor of patient motivation is the concept of compliance itself. Synonymous with terms such as *obedience*, *submission*, and *yielding*, the concept of compliance has proven to be an ineffective way to promote patient motivation. In contrast, the idea of concordance promotes an agreement between an oral health care provider and the patient about therapeutic decisions. Concordance considers the patient's needs and beliefs. Unlike compliance, the concordance mindset does not assume that patients will follow through with health-related advice simply because it is dictated by the professional. The concordance model encourages a sharing of control in the professional/patient relationship.

Numerous studies have reported the effectiveness of power toothbrushes vs their manual counterparts in the removal of plaque, reduction of gingivitis, and improvement in periodontal parameters.[16] However, the role played by the power toothbrush in enhancing the brushing experience should not be overlooked. Research indicates an increase in a patient's ability and willingness to follow the recommended regimen with power toothbrushes.[17-19] This enhanced motivation may be linked to specific design features that have been incorporated into recent power toothbrushes to promote product familiarization, brushing-time adherence, applied brushing forces, and technique.

One of the most innovative power toothbrush designs, the Sonicare® toothbrush[a], uses sonic technology to supplement direct mechanical plaque removal with dynamic fluid cleaning action. Both in vitro and in vivo research indicates that the Sonicare® toothbrush provides superior cleaning effects and meaningful oral health benefits vs manual toothbrushes.[20,21] An upgraded version of this sonic power toothbrush, the Sonicare® Elite®[a], was introduced in 2002 and maintains these features in a revised design that significantly improves ease of use and offers enhanced plaque-removal benefits.[22,23] Sonicare® toothbrushes employ system features that actively encourage a 2-minute brushing duration and proper brushing technique (Smartimer®[a] and Quad-Pacer®[a]) as well as brush adoption for new users (Easy-Start®[a]). From a concordance standpoint, these features empower the patient to more easily adopt behaviors recommended by the oral health professional, such as adequate brushing time and full-mouth technique.

Most recently, a novel technology, the IntelliClean System from Sonicare®[a] and Crest®[b], has been developed based on the Sonicare® technology platform that incorporates a dispensing system able to deliver controlled doses of a specially formulated sodium-

[a]Philips Oral Healthcare, Inc, Snoqualmie, WA 98065; 800-676-SONIC
[b]The Procter & Gamble Co, Cincinnati, OH 45202; 800-492-7378

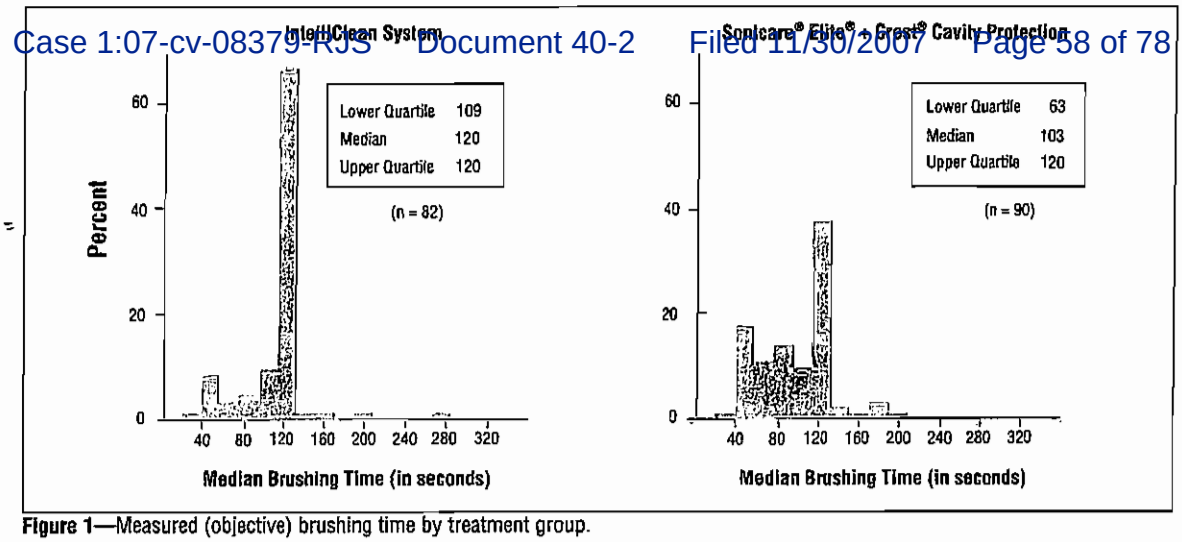

Figure 1—Measured (objective) brushing time by treatment group.

fluoride liquid toothpaste on demand.

The IntelliClean System offers a fully integrated approach to toothbrushing by combining both mechanical and chemical components into one device. Clinical research demonstrates that this novel system provides plaque reduction superior to manual brushing and significant reductions in gingivitis within 4 weeks of use.[24,25] Users also have the unique ability to redose the liquid toothpaste during the brushing cycle. This has been shown to significantly increase the effects of cleaning through the reduction of plaque bacteria in the gingival sulcus.[26] Evidence from consumer research (data on file, The Procter & Gamble Company) suggests that this integrated system also provides an enhanced user experience through a combination of perceived performance, increased convenience, and better in-use properties of the system (eg, easy and consistent dispersion of the toothpaste, fast and consistent foaming, ease of rinsing of the paste, and enhanced flavor during and after brushing). Investigating consumer brushing behavior, particularly in relation to other power toothbrushes, may provide an understanding as to why these features are so important in delivering positive oral health effects to users. The aim of this controlled study was to investigate consumer compliance to brushing instructions among users of the novel integrated oral hygiene system vs users of the Sonicare® Elite® toothbrush and conventional sodium-fluoride toothpaste.

Methods

Study Procedures

For this market research study, 356 subjects were recruited among the representative population (Delve, Minneapolis, Minnesota). They were between 18 and 55 years of age and brushed their teeth at least once a day before entering the study. A single-blind, parallel study design was used. Placement was randomized, and groups were balanced for age, gender, brushing frequency, brushing duration, and type of toothbrush used at baseline (eg, rechargeable, battery, or manual). One group was assigned the new integrated toothbrush system, the other group was assigned a Sonicare® Elite® power toothbrush and Crest® Cavity Protection[b] toothpaste. Within each group, a proportion of brushes (100) was fitted with electronic tracking devices to record actual brushing frequency and duration over the 6-week study period. The tracking devices were not known or noticeable to the subjects. Participants were asked to use the respective test product for 6 weeks at home, in place of their regular toothbrush and toothpaste. They completed a baseline habits-and-practices questionnaire and received a brief product introduction. Subjects in the nonintegrated group were instructed to brush as indicated in the Sonicare® owner's manual, which was adapted for the group using the integrated system. After 6 weeks, participants returned the products and filled in a computer-based postuse questionnaire.

Statistical Methods

Demographics and pretreatment measures were tested to ensure no significant differences between groups at baseline. Self-reported brushing times from the postuse questionnaire were compared between the two treatment legs. Data obtained from the electronic track-

ing devices were used to calculate a median brushing time and comparison between the two treatment legs. Self-reported brushing frequency on the postuse questionnaire used a five-point categorical scale. For the purposes of analysis, this was converted into a binary scale of compliant (twice per day or more) and noncompliant (less than twice per day). Statistical comparisons of the proportion of compliant respondents on each treatment leg were made. For the remaining direct questions on the postuse questionnaire, treatment means were compared using analysis of variance (ANOVA) techniques. In addition to the planned analysis, the variation in brushing time that was recorded over the course of the study was evaluated. Any change in self-reported brushing time was calculated by subtracting each subject's response at baseline from their response postuse.

Self-reported brushing time also was used to define compliance. The continuous time scale was converted into a binary scale of compliant (≥ 120 seconds) and noncompliant (< 120 seconds) for both the preuse and postuse measures. The proportion of compliant respondents on each treatment leg was compared, as was any change in compliance from preuse to postuse. All statistical significances were declared at the 2-sided, 0.05 significance level. Data were not normally distributed, so nonparametric methods were used to test for differences between treatment groups. Because of the distribution of the data and the presence of outliers, mean values were considered an unsuitable measure of location. For this reason, median values were used in the analysis.

Results

Demographics

Table 1 summarizes the demographics and baseline characteristics of the two study groups. The Fisher exact test was used to compare for age, brush type, and brushing frequency. Both groups were well balanced for these factors at baseline. Respondent-defined "screener brushing time" (seconds) is a continuous variable and hence the median and range are used as summary statistics. Again, there was no significant difference for this measure at baseline between groups.

Objective Brushing Time

The median brushing time over the course of the study was calculated for each respondent to provide a single measure of brushing time. The median of these values was then taken, along with the lower and upper quartiles, to give an overall summary for each treatment group (Figure 1). The overall median brushing time for users of the integrated system was 120 seconds, compared with 103 seconds for nonintegrated users. The central 50% of the data from users of the integrated system fell between 109 and 120 seconds compared to the control-group data, where the central 50% fell between 63 and 120 seconds. Users of the integrated system had a significantly longer median brushing time than the nonintegrated users (P = .018). More than 60% of the subjects using the integrated system brushed for approximately 120 seconds during each period of use. Overall, there was a significantly higher proportion of compliant integrated system users (70.7%) than nonintegrated users (45.6%) at postuse (P = .001).

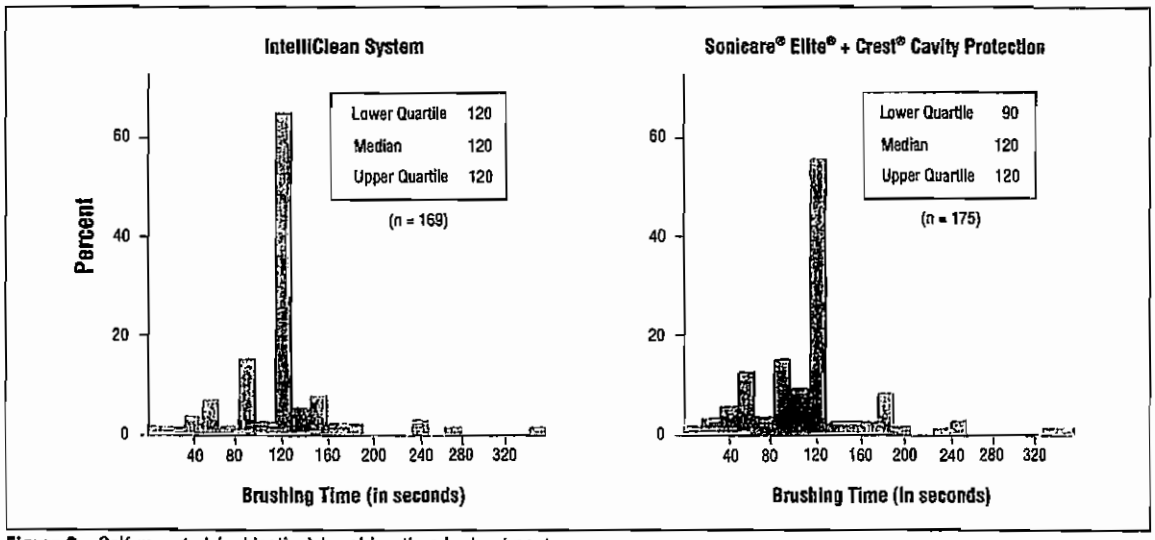

Figure 2—Self-reported (subjective) brushing time by treatment group.

Self-reported Brushing Time

Postuse brushing time: On the postuse questionnaire, respondents were asked to state for how long they had brushed their teeth, on average, each time over the past week. The response was given as a specific length of time in seconds (Figure 2). While both treatment groups had a median value of 120 seconds, the central 50% of the integrated group data was all equal to 120 seconds; whereas the central 50% of the nonintegrated group data was more spread, ranging from 90 to 120 seconds. More than 60% of the integrated users reported brushing for 120 seconds. Compared to the integrated group, a significantly higher proportion ($P = .0475$) of nonintegrated users reported brushing for less than 120 seconds.

Change in brushing time: Change in self-reported brushing time was calculated by subtracting each respondent's self-reported brushing time at baseline from the same measure postuse. A positive result indicated that the respondent's self-reported brushing time increased over the study. A negative result indicated that the brushing time decreased, and a result of zero indicated no change (Table 2). Overall, the self-reported brushing in the integrated group increased significantly more than that of the nonintegrated group. In the integrated group, at least 75% of the change in brushing times was positive, demonstrating an increase in respondents' brushing times, with the median value being 30 seconds. In comparison, the central 50% of the control group data fell between –15 seconds and 40 seconds, with the median value being zero.

Brushing time to define compliance: At both baseline and postuse, respondents were asked to state their average brushing time over the past week. These data were converted from continuous form into a binary scale defining compliant and noncompliant respondents. Respondents with reported brushing times of 120 seconds or more were defined as compliant, while those with brushing times less than 120 seconds were defined as noncompliant (Figure 3). Changes in compliance were evaluated based on differences in reported brushing times at baseline and postuse. The integrated group had a significantly higher proportion of respondents whose compliance increased by the end of the study ($P = .0016$).

Self-reported Brushing Frequency

When analyzing the full population, there was a less than 1% difference in the proportion of compliant respondents between the integrated and the nonintegrated groups (84% and 83.4%, respectively). When subjects who did not use the assigned system or used another brush were removed, there was an approximately 4% difference in the proportion of compliant respondents between the integrated and the nonintegrated groups (84.6% and 80.7%, respectively). Because of a technical hardware problem, an objective measure of brushing frequency could not be derived from this study. Because the tracking devices drained the brush charge more than was foreseen, the number of recorded brush-user interactions could not be directly translated into the number of brushing occasions.

Analysis of Product Attributes

Questions were asked on the categorical scales indicated in Table 3. ANOVA was used to compare the two treatment groups. The integrated product scored significantly higher than the control product in Overall Rating, Relative Category Rating, Brushing Less of a Chore, Convenience of Using the System, and Messiness of System.

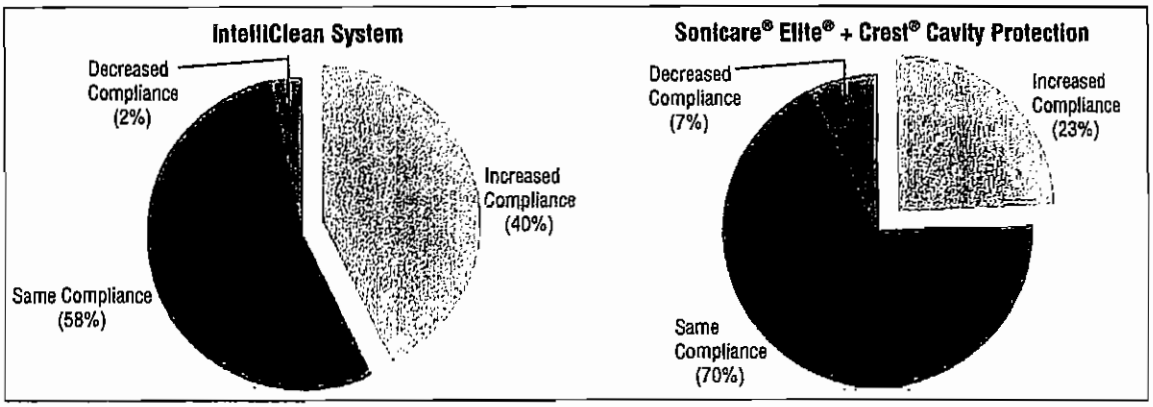

Figure 3—Change in brushing compliance postuse vs baseline by treatment group.

IntelliClean System (n = 169)	0	30	60
Sonicare® Elite® + Crest® Cavity Protection (n = 175)	–15	0	40

Discussion

The results of this study indicate that, in both test groups, subjects brushed their teeth for significantly longer than the commonly observed brushing time for manual toothbrush users. In fact, several studies in which subjects' toothbrushing behavior with a manual brush was recorded with or without their knowledge revealed brushing times ranging from 33 to 84 seconds.[27-30] In particular, Emling et al reported observing an average brushing time of 56.7 seconds when patients brushed at intake to a university dental clinic and were timed without their knowledge.[27] In the present study, both the integrated and nonintegrated power toothbrush systems show brushing times much longer than those reported for manual brushing. The results of this study also indicate significant differences in the objectively measured and subject-perceived brushing times between the novel integrated system and the control (nonintegrated power toothbrush and toothpaste). Over the duration of the study, subjects using the integrated system demonstrated a 15% greater brushing time than the nonintegrated system. In terms of actual time, this equates to full compliance with the recommended 120 seconds per brushing episode for the integrated system vs 103 seconds for the nonintegrated system over the duration of the study. The self-reported results indicate a similar trend, with more than 75% of subjects stating they maintained the recommended brushing time in the integrated group vs 60% among the nonintegrated group.

It should be noted that the discussed differences in brushing time were observed although both power toothbrushes tested in this study have the same timer features to encourage a 2-minute brushing duration (Smartimer® = automatic switch off after 120 seconds; QuadPacer® = timer signal every 30 seconds).

While it is difficult to interpret the clinical significance of this increased compliance, we may speculate that the level of cleaning efficacy in the long term might be affected as increased brushing times have been directly correlated to better plaque removal.[31] The results derived from the self-reported data are comparable to those generated using the objective tracking devices. A common problem in research of this nature is the lack of correlation between subject-estimated and objectively recorded brushing times.[27,32] In this study, the fact that both measures provided similar outcomes imparts confidence in the inferences derived from the subjective results.

Interestingly, when changes in brushing time are evaluated over the course of the study, there is a significant increase among users of the integrated system vs the nonintegrated system. In fact, there was no reported change in median brushing time for the nonintegrated users over the course of the study. In terms of compliance, approximately 40% of the integrated group improved their brushing times by the end of the study vs only 23% of the nonintegrated group. This outcome may be important in understanding how an improved brushing experience affects motivation.

Surprisingly, self-reported frequency of brushing did not show any significant differences between products, with more than 80% of the subjects in both groups reporting adherence to the recommended 2 episodes of brushing. However, it was not possible to derive an objective measure of brushing frequency from the tracking devices because of a technical failure in the hardware. Given the previously reported inconsistencies between subjective and objective measures, these results would have been useful to place the reported data into context. Hopefully, future research will clarify changes in the frequency of toothbrushing for this type of product.

Some studies have indicated a steady fall in brushing frequency after 2 months of power toothbrush use.[33,34] This study was relatively short in length, but it is of clear interest in furthering understanding of the effects on motivation in long-term use of an integrated toothbrush/toothpaste system. Research investigating the brushing compliance with the IntelliClean System over a longer period of time—up to 6 months—is ongoing and will be reported separately. Regular den-

	IntelliClean System	Sonicare Elite + Crest Daily Protection
	n = 169 a	n = 175 b
Q1 Overall Rating	2.86 b	2.50
Scored on a 9-point scale with –4 = Dislike extremely, +4 = Like extremely		
Q4 Relative Category Rating (RCR)	4.49 b	4.15
Scored on a 5-point scale with 1 = Worst system tried, 5 = Best system tried		
Q8a Brushing less of a chore	1.06 b	0.70
Q8b Brush teeth more often	0.27	0.12
Q8c Brush teeth for longer	1.09	0.96
Scored on a 5-point scale with –2 = Strongly disagree, +2 = Strongly agree		
Q9a Ability to clean overall	3.15	2.87
Q9b Ability to clean between teeth	2.52	2.41
Q9c Ease of using the system	2.75	2.70
Q9d Convenience of using system	3.12 b	2.68
Q9e Messiness of system	1.53 b	0.92
Scored on a 9-point scale with –4 = Dislike extremely, +4 = Like extremely		
Q10 Change in health of teeth and gums	1.17	1.05
Scored on a 5-point scale with –2 = Much worse, +2 = Much better		
Q5 How often you brushed teeth per day	84.0%	83.4%
Proportion of "compliant" respondents—brushing twice or more per day		

Letter indicates that the product scored significantly higher than the product indicated, at a 95% confidence level.

tal visits, appropriate to an individual's oral condition and involving repeated instruction and motivation by the professional, also should help with longer-term compliance.

Factors driving motivation are varied and have been the subject of much research. A number of models have been proposed to characterize compliance and the factors by which it is affected.[35-38] Although a definitive example is still outstanding, a common thread in many of these models is the role satisfaction plays. This study is particularly relevant when looking at the level of satisfaction at the product/patient interface. While there was no observed difference between treatments in terms of perceived product efficacy (cleaning, change in health), the integrated system scored significantly higher than the control in use-related attributes (convenience, messiness). A more emotional measure of product rating was gained from the statement that toothbrushing had become less of a chore, in which, again, the integrated system scored significantly higher than the nonintegrated brush. The mentioned attributes are key to understanding the overall acceptance of the integrated system as seen in this study. Turning an everyday necessary treatment into an enjoyable experience can motivate patients to better comply with the recommended treatment regimen. In this respect, the integrated toothbrush/toothpaste system appears to offer a clear and distinct advantage over other toothbrushing alternatives.

When the concordance model is applied to this study, it is apparent that the motivational features of the integrated system enhance concordance. While the concordance concept is derived from the medical community (ie, the failure of patients to take prescribed medications), it is a fitting approach for the promotion of better oral hygiene.[39-41] Concordance advocates a sharing of power in the professional/patient relationship. Therefore, a device that promotes the professional's recommendations (eg, 2-minute brushing time, full-mouth technique, adequate toothpaste dispensing) in a manner that facilitates these actions by the patient furthers an atmosphere of concordance.

Conclusion

This research has demonstrated that the novel integrated power toothbrush/toothpaste system, the IntelliClean System from Sonicare® and Crest®, significantly improved oral hygiene compliance with brushing instructions vs a conventional power toothbrush and toothpaste combination. The results also indicated a significantly higher level of user acceptance for the integrated system compared to the nonintegrated power toothbrush plus toothpaste combination. Further research is required to understand the concordance/motivation profile over longer time periods as well as the possible applications of the system in specific patient populations.

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The Procter & Gamble Company supported this research.

Acknowledgments

The authors thank Lorraine Bourke of The Procter & Gamble Company and Dr. Douglas Dudgeon of Philips Oral Healthcare, Inc, for their contributions to this research.

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Stain Reduction of an Integrated Oral Hygiene System

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Abstract: ***This article discusses research to determine the efficacy of a prototype integrated power toothbrush and toothpaste dispensing system, the IntelliClean System from Sonicare® and Crest®, in the removal of extrinsic stain. The prototype integrated system and a positive control, the Sonicare® Elite® with conventional toothpaste, were evaluated in 2 randomized, single-blinded, parallel 4-week controlled clinical trials. There was a low dropout rate, with 28 subjects of the 31 randomized in study 1 completing the study (10% loss to follow-up) and 26 subjects of the 28 randomized in study 2 completing the study (7% loss to follow-up). Lobene stain scores were used to assess the extent and intensity of stain for all teeth meeting the criteria for inclusion in the studies. Lobene stain scores were assessed at baseline and after 4 weeks in both studies. A survey also was conducted at the conclusion of each study to determine user attitude toward the integrated system. The prototype integrated system was found to significantly reduce overall extrinsic stain over time, performing not significantly differently from the positive control. Overall, the prototype integrated system reduced the composite measure of stain that encompasses both the extent and intensity of stain by 60%. This research demonstrates that the IntelliClean System from Sonicare® and Crest® is highly effective in reducing extrinsic stain.***

Tooth color continues to be of esthetic importance to many people. Over the past 15 years, both in-office and direct-to-consumer bleaching have become more and more commonplace, particularly in the United States, as patients seek whiter teeth to improve their overall appearance. Up to 90% of US dental practices now offer vital tooth bleaching,[1] and teeth whitening, including direct-to-consumer bleaching products such as Crest® Whitestrips[a], has become a $600-million business.[2] In practice, bleaching is indicated for the reduction of overall stain, both the extrinsic stains on the surface of teeth and the intrinsic stains that may be incorporated into the tooth structure. For many patients, the removal of extrinsic stain alone is sufficient to bring about the desited whiteness in tooth color, and even for patients with bleached teeth, extrinsic stain removal may be important for maintaining optimal color of the dentition. The dental professional readily removes extrinsic stain during routine prophylaxis by polishing the teeth with an abrasive-containing paste. Patients also may remove extrinsic stain through better oral hygiene alone or combined with direct-to-consumer whitening products.

Power toothbrushes have been demonstrated in clinical trials to remove extrinsic stain when used with regular toothpaste products, and the Sonicare® power toothbrush[b] was among the first to be examined in this regard. In 1994, McInnes and colleagues[3] reported that use of the sonic toothbrush resulted in an 82% reduction in naturally occurring coffee, tea, and tobacco stains after 4 weeks and a 50% reduction in stain induced by regular use of a 0.12% chlorhexidine mouth rinse in a similar period. In

[a]The Procter & Gamble Co, Cincinnati, OH 45202; 800-492-7378
[b]Philips Oral Healthcare, Inc, Snoqualmie, WA 98065; 800-676-SONIC

Lobene Stain Index	
Area Index	
0	No stain detected, only tooth color
1	Stain in up to 1/3 of the region
2	Stain in over 1/3 but less than 2/3 of the region
3	Stain in over 2/3 of the region
Intensity Index	
0	No stain; clean and natural color
1	Light stain; slight yellowish to tan color that can be seen with close examination
2	Moderate stain; obvious brownish discoloration
3	Heavy stain; heavy brown to black discoloration

Labial surface of each incisor is divided into two regions, margin and body. Margin and body regions are scored separately for stain. The margin is the gingival region of the tooth from the gingival margin to an imaginary line connecting the tips of the adjacent papillae. The body is the remainder of the tooth above the line connecting papillae tips. The stain in each region is scored 0 to 3 for area and 0 to 3 for intensity.

another study, the Braun Oral-B® 3D Plaque Remover[c] and the Sonicare® Plus[b] power toothbrushes were investigated to determine the ability of each to remove naturally occurring extrinsic stain. After 6 weeks of use, both types of power toothbrushes produced statistically significant reductions in stain ($P < .001$).[4] More recently, Terézhalmy et al[5] reported 4 independent clinical studies to determine the effectiveness of the Crest® SpinBrush™ Pro Whitening[a] and Sonicare® Advance 4100[b] power toothbrushes in removing extrinsic stain after 2 weeks of brushing. Again, both products were found to significantly reduce extrinsic stain ($P < .05$) with stain scores reduced by 44% to 88% compared to baseline. A study by Drisko and colleagues found that the Sonicare® Elite® power toothbrush[b] significantly reduced extrinsic stain over 4 weeks in both intensity ($P < .001$) and area ($P = .002$) (data on file, Philips Oral Healthcare, Inc).

Both in-office and direct-to-consumer bleaching have become more and more commonplace in the United States, as patients seek whiter teeth to improve their overall appearance.

The IntelliClean System from Sonicare® and Crest® is a new integrated sonic power toothbrush and liquid-toothpaste dispensing system. The toothpaste is formulated with a special consistency that allows the gel to be liquefied rapidly by the system's high-speed bristle motion. A pump in the handle of the toothbrush allows the user to re-dose toothpaste during brushing, for targeting cleaning in hard-to-reach areas of the mouth. The toothbrush maintains the same patented sonic technology of previous Sonicare® products.[6] The primary objective of the current 2 studies was to assess whether a prototype version of the new integrated system demonstrated significant extrinsic-stain reduction over a 4-week period.

Materials and Methods

Overview

Two parallel, single-blinded, randomized, controlled clinical trials were conducted to determine the efficacy of the prototype integrated system in stain reduction after 4 weeks of product use according to the manufacturer's instructions. Stain reduction was investigated through clinical visual examinations using the Lobene stain index (Table 1).[7] Intraoral photographs were taken at baseline and at 4 weeks. Independent study sites were used for each study, with the same calibrated examiner evaluating and scoring subjects at both sites.

Each study used the same inclusion/exclusion criteria. For inclusion in the study, subjects had to have at least 18 teeth with 10 natural anterior teeth (ie, no large restorations or crowns on anterior teeth) and have esthetically noticeable stain with an average composite Lobene score of 1.5 or greater on the facial surfaces of at least 4 anterior teeth without significant recession or malocclusion.

The examiner was blinded to the assigned treatment group. Before visit 1, the examiner was calibrated for accuracy and repeatability

[c]Oral-B Laboratories, Boston, MA 02127; 800-446-7252

using the modified Lobene stain index on a population equivalent to those selected for the study.

Human Subjects Consideration

All subjects were required to read, sign, and date the informed consent form approved by the Institutional Review Board before starting the study. Subjects were also instructed to call the telephone number provided on the informed consent form in case of any suspected adverse effects. Subjects were examined as indicated in the flowchart in Figure 1.

Treatment Groups

Control group (nonintegrated system): Subjects randomized to the control group were provided with a Sonicare® Elite® toothbrush and Crest® Cavity Protection Cool Mint Gel toothpaste* with active ingredient sodium fluoride (0.243% weight). They were provided with detailed brushing instructions and also were told to brush their teeth throughout the course of the study twice a day for 2 minutes plus an additional 30 seconds on the facial surfaces of the anterior teeth. No additional oral hygiene aids, such as floss, mouth rinses, etc, were to be used throughout the course of the study. No attempt was made to mask the identity of either the toothbrush or the toothpaste.

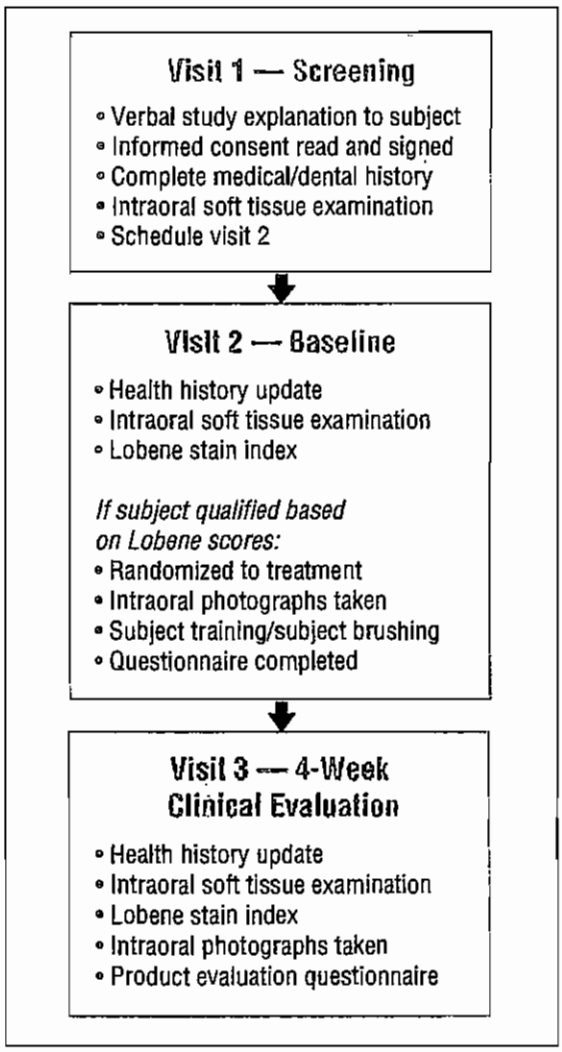

Figure 1—Flowchart of study.

For many patients, the removal of extrinsic stain alone is sufficient to bring about the desired whiteness in tooth color.

Test group (prototype integrated system): Subjects randomized to the integrated system group were provided with a prototype IntelliClean System. The toothbrush part of the prototype system was identified with a label designating it as an "investigational product," with a 24-hour telephone number for questions and to report problems. The directions for use of the prototype integrated system and the informed consent form also clearly stated that the toothpaste was a prototype and provided a 24-hour telephone number for questions and/or concerns. The toothbrush in the integrated system is manufactured by Philips Oral Healthcare, Inc, and is built on the company's Sonicare® brushing technology. The integrated system toothbrush incorporates high-frequency bristle motion with a 2-minute timer and an audible indication every 30 seconds during brushing to signal the user to move the brush from quadrant to quadrant for a more even distribution of brushing time. It additionally incorporates a push-button pump to allow the user to dispense toothpaste into the toothbrush bristles before and during brushing from a toothpaste cartridge that is integrated into the device.

The toothpaste for the prototype integrated system is a sodium-fluoride liquid toothpaste manufactured by The Procter & Gamble Company. (A whitening liquid toothpaste for the IntelliClean System also exists but was not used in these studies.) It is manufactured in accordance with good manufacturing practices and federal regulations concerning fluoride-based anticaries toothpaste. The prototype toothpaste was packaged within 15-mL volume soft-side cartridges that fit into the prototype device. Each toothpaste cartridge was labeled

Table 2—Descriptive Statistics for Baseline Lobene Stain by Treatment Group

	Study 1 Mean ± SD	Study 2 Mean ± SD	Both Studies Mean ± SD
Margin Intensity			
Sonicare® Elite® w/toothpaste	1.57 ± 0.46	1.42 ± 0.29	1.51 ± 0.40
IntelliClean System	1.56 ± 0.71	1.47 ± 0.34	1.52 ± 0.54
Margin Extent			
Sonicare® Elite® w/toothpaste	1.36 ± 0.36	1.23 ± 0.29	1.31 ± 0.30
IntelliClean System	1.32 ± 0.41	1.52 ± 0.39	1.42 ± 0.41
Margin Composite			
Sonicare® Elite® w/toothpaste	2.14 ± 0.76	1.77 ± 0.47	2.00 ± 0.67
IntelliClean System	2.10 ± 1.07	2.31 ± 0.90	2.21 ± 0.98
Body Intensity			
Sonicare® Elite® w/toothpaste	2.04 ± 0.62	2.06 ± 0.29	2.04 ± 0.51
IntelliClean System	2.04 ± 0.61	1.98 ± 0.43	2.01 ± 0.52
Body Extent			
Sonicare® Elite® w/toothpaste	1.10 ± 0.13	1.17 ± 0.27	1.12 ± 0.19
IntelliClean System	1.08 ± 0.16	1.16 ± 0.21	1.12 ± 0.19
Body Composite			
Sonicare® Elite® w/toothpaste	2.30 ± 0.77	2.32 ± 0.44	2.31 ± 0.65
IntelliClean System	2.22 ± 0.73	2.27 ± 0.54	2.24 ± 0.63
Overall Intensity			
Sonicare® Elite® w/toothpaste	1.80 ± 0.42	1.74 ± 0.24	1.78 ± 0.36
IntelliClean System	1.89 ± 0.54	1.72 ± 0.30	1.76 ± 0.43
Overall Extent			
Sonicare® Elite® w/toothpaste	1.23 ± 0.19	1.20 ± 0.14	1.22 ± 0.17
IntelliClean System	1.20 ± 0.26	1.34 ± 0.28	1.27 ± 0.28
Overall Composite			
Sonicare® Elite® w/toothpaste	2.22 ± 0.58	2.05 ± 0.37	2.15 ± 0.51
IntelliClean System	2.16 ± 0.78	2.29 ± 0.61	2.23 ± 0.69

SD = standard deviation.

with a nonremovable clinical test label listing a reference to usage directions, the active ingredient and its concentration (sodium fluoride, 0.243% weight), as well as a 24-hour telephone number for any questions or concerns.

The prototype integrated system was supplied as a kit. Subjects randomized to the integrated system were supplied with one complete white power toothbrush and one charger plus four toothpaste cartridges to be used over the course of the study. No brand identification was made on any part of the integrated system.

Study Population

Because the primary focus of the two studies was to evaluate the efficacy of the prototype integrated system, subjects were randomized in blocks of four, with three randomized to the integrated system (test) and one randomized to the nonintegrated system (control). For study 1, 31 subjects were randomized and enrolled, and 29 (93.5%) completed the study. For study 2, 28 subjects were randomized and enrolled, and 26 (92.9%) completed the study. With both studies combined, a total of 59 subjects were randomized and enrolled, with 55 subjects (93.2%) completing the 2 studies. Of the four subjects that dropped out of the study, three were in the integrated group and one was in the nonintegrated group.

Statistical Analysis

Subject means were calculated for margin, body, and overall Lobene scores for extent of stain, intensity of stain, and a composite score representing both extent and intensity of stain. The composite Lobene scores were calculated by taking the product of the Lobene scores for the corresponding extent of stain and intensity of stain. Descriptive statistics were calculated for all baseline Lobene scores. Percent stain reduction over 4 weeks was calculated for each subject. Analysis of covariance (ANCOVA) was used to obtain the adjusted mean percent stain reduction over 4 weeks.

Statistical analysis was conducted for each

study individually. Then data from the two studies were combined and analyzed together. A term for the study site was included where a significant difference between studies was detected.

Results

For study 1, 14 of the 19 subjects (73.7%) in the integrated group (test) were women, and 5 of the 10 subjects (50%) in the nonintegrated group (control) were women. The mean age of the 19 subjects in the integrated group was 46.2 (standard deviation [SD] = 8.43, median = 47 years, range = 34 to 68 years), whereas the mean age of the 10 subjects in the nonintegrated group was 45.6 (SD = 13.8, median = 48.5 years, range = 21 to 65 years).

For study 2, 14 of the 20 subjects (70%) in the integrated group were women, and 2 of the 6 subjects (33.3%) in the nonintegrated group were women. The mean age of the 20 subjects in the integrated group was 47.3 (SD = 9.54, median = 45.5 years, range = 34 to 68 years), whereas the mean age of the 6 in the nonintegrated group was 37.8 (SD = 5.88, median = 39.5 years, range = 29 to 43 years).

With respect to intraexaminer reliability, statistical testing of repeated stain scores showed that the weighted kappa statistic, an indication of agreement among examinations, was 0.77. A kappa statistic of 0.75 and above represents excellent agreement.[8]

Mean Lobene scores (extent and intensity) were calculated for each subject for both the body of the tooth and the margin of the tooth at baseline. Composite Lobene scores were obtained from the product of the extent and intensity, and mean composite Lobene scores also were calculated for each subject for both the body of the tooth and the margin of the tooth at baseline. Overall mean Lobene scores that were computed from the body and margin scores also were computed for extent, intensity, and composite at baseline. Descriptive statistics

Table 3—Descriptive Statistics for Percent Reduction in Lobene Stain Over 4 Weeks

	Study 1 Mean ± SD	Study 2 Mean ± SD	Both Studies Mean ± SD
% Reduction in Margin Intensity			
Sonicare® Elite® w/toothpaste	55.2 ± 28.6	61.5 ± 36.0	57.6 ± 30.5
IntelliClean System	46.6 ± 25.9	57.9 ± 27.1	52.4 ± 26.8
% Reduction in Margin Extent			
Sonicare® Elite® w/toothpaste	48.9 ± 30.9	55.4 ± 38.8	51.3 ± 32.9
IntelliClean System	45.6 ± 35.4	63.0 ± 24.2	154.5 ± 31
% Reduction in Margin Composite			
Sonicare® Elite® w/toothpaste	62.3 ± 22.2	65.0 ± 36.2	63.3 ± 27 1
IntelliClean System	57.6 ± 23.1	68.8 ± 20.2	63.3 ± 22.1
% Reduction in Body Intensity			
Sonicare® Elite® w/toothpaste	53.8 ± 19.4	38.0 ± 20.8	47.9 ± 20.8
IntelliClean System	62.8 ± 18.6	43.4 ± 32.1	52.8 ± 27.8
% Reduction in Body Extent			
Sonicare® Elite® w/toothpaste	29.3 ± 31.4	24.4 ± 20.6	27.5 ± 27.2
IntelliClean System	49.3 ± 20.4	34.2 ± 27.1	41.6 ± 24.9
% Reduction in Body Composite			
Sonicare® Elite® w/toothpaste	57.2 ± 16.2	43.0 ± 17.8	51.8 ± 17.7
IntelliClean System	65.2 ± 16.7	49.2 ± 28.5	57.0 ± 24.6
% Reduction in Overall Intensity			
Sonicare® Elite® w/toothpaste	52.9 ± 14.2	46.9 ± 24.7	50.6 ± 18.2
IntelliClean System	56.5 ± 11.9	48.9 ± 23.2	52.6 ± 18.7
% Reduction in Overall Extent			
Sonicare® Elite® w/toothpaste	39.6 ± 17.7	41.7 ± 23.6	40.4 ± 19.3
IntelliClean System	48.6 ± 19.4	49.3 ± 11.8	49.0 ± 15.7
% Reduction in Overall Composite			
Sonicare® Elite® w/toothpaste	58.4 ± 11.9	52.8 ± 21.8	56.3 ± 15.8
IntelliClean System	62.5 ± 10.5	57.5 ± 17.2	59.9 ± 14.4

SD = standard deviation.

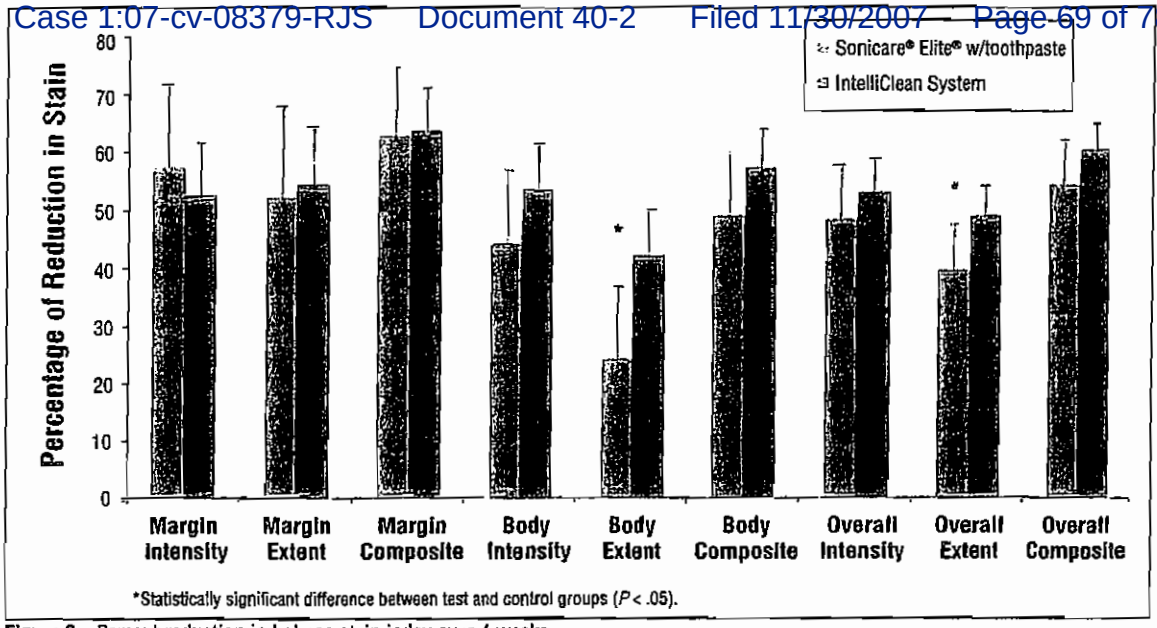

Figure 2—Percent reduction in Lobene stain index over 4 weeks.

were calculated for each study individually as well as for the two studies combined for these baseline Lobene scores by treatment group. Means and standard deviations are presented for all Lobene scores by treatment group and study in Table 2.

Changes in Lobene scores over 4 weeks were calculated for intensity, extent, and composite for margin, body, and overall stain for each subject. Mean changes in these Lobene scores for both integrated and nonintegrated groups were tested using paired *t* tests. Significant reductions in intensity, extent, and composite (product of intensity and extent) Lobene scores for margin, body, and overall stain for both the integrated group and the nonintegrated group over 4 weeks were detected ($P < .001$ for all measures and all groups). Percent reductions in intensity, extent, and composite Lobene scores for margin, body, and overall stain over 4 weeks also were calculated for each subject. Mean percent reductions in these Lobene scores with corresponding standard deviations are presented in Table 3 for each study individually as well as for both studies pooled together. ANCOVA was conducted to test whether there was a difference in the percent reduction over 4 weeks between the integrated group and the nonintegrated group with age and corresponding baseline Lobene scores included as covariates as well as testing for differences between the two studies. The only statistically significant differences that were detected were in the pooled data for the percent reduction in the extent of body stain ($P = .023$) and the percent reduction in the extent of overall stain ($P = .049$), with the integrated group exhibiting a greater reduction in the extent of body stain and extent of overall stain than the nonintegrated group. The adjusted means with 95% confidence intervals for the percent reductions in these Lobene scores by treatment group are shown in Figure 2.

Power toothbrushes have been demonstrated in clinical trials to remove extrinsic stain when used with regular toothpaste products.

There were 2 oral adverse events (AEs) and 3 non-oral AEs in study 1. All were deemed by the principal investigator to be mild in severity and not related to the study products. In study 2, there was 1 oral AE, a case of gum irritation for a subject in the integrated system group. This AE was judged by the principal investigator to be mild in severity and possibly related to the test product, and it was resolved 2 days after the final product use. There were no serious AEs in either study.

Questionnaire Response

Thirty-nine subjects in the integrated system group (19 subjects in study 1 and 20 subjects in

Table 4. Distribution of Questionnaire Responses for the Integrated System for Each Study

	Study 1	Study 2
Using the study toothbrush and toothpaste made my teeth feel "just from the dentist" clean.		
No	15%	15%
Yes	74%	75%
No difference	11%	10%
By the end of the study, I noticed that my teeth were whiter.		
No	11%	15%
Yes	74%	75%
No difference	16%	10%
The study toothbrush and toothpaste made my teeth feel cleaner than my usual toothbrush and toothpaste.		
No	11%	20%
Yes	84%	80%
No difference	5%	0
The study toothbrush and toothpaste were gentler on my gums than my usual toothbrush and toothpaste.		
No	16%	20%
Yes	42%	55%
No difference	42%	25%
I liked the study brush and paste better at the end of the study than at the start.		
No	5%	5%
Yes	63%	70%
No difference	32%	25%
By the end of the study, I had less bleeding from brushing and flossing.		
No	5%	0
Yes	26%	60%
No difference	68%	40%
By the end of the study, the brush vibration was comfortable.		
No	0	10%
Yes	84%	75%
No difference	16%	15%
By the end of the study, the brush had become easier to use.		
No	0	5%
Yes	84%	85%
No difference	16%	10%
I liked the study brush and paste better than my usual brush and paste.		
No	11%	20%
Yes	74%	75%
No difference	16%	5%

study 2) responded to the questionnaire. Table 4 shows the distribution of responses by study. A poststudy questionnaire was not administered to the control group because of the extremely small number of subjects in that group. It was felt that it would not be useful or informative to present data from this group because statistical comparisons could not be made.

No significant difference in response was detected between the two groups. Overall, three quarters of the subjects using the prototype integrated system indicated that their teeth were "just from the dentist" clean, their teeth were whiter, and they preferred the integrated system to their usual toothbrush and toothpaste. At least 80% responded that the integrated system made their teeth feel cleaner than their usual toothbrush and toothpaste.

Discussion

These 2 studies demonstrated that the prototype integrated system is highly effective in reducing stain over a 4-week period, with a significant reduction in all Lobene scores exhibited by the integrated system over the study period. Observed reductions in stain for the integrated system are comparable to the stain reduction achieved with the nonintegrated system of the sonic toothbrush and conventional toothpaste. The only statistically

significant differences noted between the integrated and nonintegrated systems were for the extent of body stain and the extent of overall stain, with the integrated system performing significantly better in these two instances. The integrated system resulted in a 49% reduction in the extent of stain, a 53% reduction in the intensity of stain, and a 60% reduction in the composite measure of stain that encompasses both extent and intensity of stain. This reduction in stain also is comparable to the results of earlier stain studies of power toothbrushes.[3-5]

Responses to the questionnaire demonstrate that subjects felt that the integrated system was highly effective in whitening their teeth, with very few indicating at the end of the study discomfort from vibration or persistent irritation and bleeding from using the system. The low number of AEs possibly or probably related to treatment for the integrated group substantiates the safety of the integrated system.

Conclusion

Over the 4-week period of the study, regular use of the prototype IntelliClean System demonstrated a 60% reduction in stain. There were very few AEs related to the IntelliClean System and all AEs were mild and temporary in duration, which validates the safety of this system. The stain reduction observed for the IntelliClean System was comparable to the stain reduction observed in previous studies of other powered toothbrushes. The prototype IntelliClean System from Sonicare® and Crest® is a highly effective device for removing extrinsic stain and was well received by most people.

Disclosures

These studies were conducted at Hill Top Research, Inc, West Palm Beach, Florida, and Miamiville, Ohio, and were sponsored by Philips Oral Healthcare, Inc.

Acknowledgment

The authors thank Ashley Barlow of The Procter & Gamble Company for his assistance.

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PG007097

In Vitro Evaluation of the Efficacy and Safety of the IntelliClean System: Interproximal Biofilm Removal and Dentin Substrate Wear

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Abstract: ***The ability of a novel integrated power toothbrush and liquid-toothpaste dispensing system, the IntelliClean System from Sonicare® and Crest®, to remove interproximal biofilm while being gentle on dentin was studied using two in vitro models. Interproximal biofilm removal was assessed via a complex multispecies biofilm grown on hydroxyapatite disks and then placed interproximally in a typodont section modeling a typical oral environment. The power toothbrush in the prototype integrated system was compared to a traditional rotating/oscillating power toothbrush, the Oral-B® ProfessionalCare 7000, and a nonbrushing control through a series of 3 experiments with a total of 36 replicates per arm. The amount of interproximal plaque biofilm removed by the integrated system toothbrush was significantly greater than that removed by the rotating/oscillating toothbrush and by the nonbrushing control (P < .05). In the second model, dentin substrate wear was measured using profilometry after the brushing of dentin sections (3 mm x 10 mm) for a period equivalent to 2 years of typical product use. Dentin wear associated with the use of the prototype integrated system with standard and whitening versions of the liquid toothpaste was compared to that of a rotating/oscillating power toothbrush and a manual toothbrush with the standard version of the prototype liquid toothpaste, with a total of 12 replicates per arm. The amount of dentin wear induced by the integrated system with either the standard or whitening liquid toothpaste was significantly less than the wear from the rotating/oscillating power toothbrush and the manual toothbrush with the standard liquid toothpaste (P < .05).***

The health of the oral cavity relies primarily on diligent oral hygiene. The number of oral hygiene products available to the public has been increasing rapidly in recent years. Elucidation of product efficacy and safety is needed as technological advances result in more effective oral hygiene devices. Dental professionals and consumers need data to make informed decisions and thus require adequate support for a product's ability to maintain oral hygiene while being safe for extended use. Additionally, comparative information to alternative products allows the user to choose the product best suited to meet specific oral hygiene needs.

The power toothbrush category of oral hygiene products has experienced a tremendous surge in options available to the consumer. The introduction of the Sonicare®,* in 1992 and the Sonicare® Elite®,* in 2002 have brought innovative features and bristle motions to power toothbrushes. These innovations

*Philips Oral Healthcare, Inc, Snoqualmie, WA 98065; 800-676-SONIC

have led to significant improvements in oral hygiene.[1-4] Target objectives achieved with Sonicare® Elite® included increased cleaning efficacy, better access to hard-to-reach areas, and improved user experience through ergonomic design and a smarter feature set.[5] As sonic toothbrush technology evolves and builds on previous accomplishments, a new generation emerges that continues to target all areas of cleaning in the oral cavity—both easy-to-reach and hard-to-reach plaque. The IntelliClean System from Sonicare® and Crest®,[b] integrates an advanced sonic toothbrush technology and a liquid-toothpaste dispensing system to target interproximal plaque.

Early studies provided evidence that fluid forces induced by Sonicare® toothbrushes remove oral biofilm from in vitro dental surfaces.[6-8] As methodology developed, the biofilm was placed in the interproximal space of a typodont model to specifically assess dental-plaque removal efficacy in areas ordinarily inaccessible to the contact of toothbrush bristles.[9] In two subsequent studies, it was determined that the fluid forces associated with the Sonicare® toothbrushes removed more interproximal biofilm than toothbrushes using the rotating/oscillating technology of the Braun Oral-B® 3D Plaque Remover pulsating toothbrush[c].[10,11] The patented range of bristle-tip velocities associated with the amplitude and frequency of bristle-tip motion generates the Sonicare® toothbrush's hydrodynamic fluid forces and is maintained within the IntelliClean System (data on file, Philips Oral Healthcare, Inc).

Elucidation of product efficacy and safety is needed as technological advances result in more effective oral hygiene devices.

Safety also is a concern with any oral hygiene regimen. The wear of exposed dentin as a result of toothbrush and toothpaste use is a well-established area of concern, whereas the wear of enamel and dental materials is a lesser concern.[12-15] As the IntelliClean System is a combination of new brushing technology and new chemistry, it is important to show not only its efficacy but also to consider its safety as an oral care product. Because toothbrushing with toothpaste is the most common method of plaque and extrinsic-stain removal,[16] it is appropriate to test both products together for safety. Previous research has indicated that the Sonicare® toothbrush, when tested with a common toothpaste, results in less dentin-abrasion wear than both an oscillating/rotating power toothbrush and a manual toothbrush.[17]

The purpose of the current in vitro studies was to investigate the ability of a prototype integrated system both to reduce interproximal dental-plaque biofilm and to remain gentle on dentin. These studies were accomplished by using in vitro models and methods closely related to those previously published for evaluating these attributes in power toothbrushes.[10,17]

Biofilm Reduction Experiments

Materials and Methods

The biofilm reduction tests conducted closely followed the methodology employed by Hope and Wilson.[10] This methodology was developed to assess the ability of fluid-induced forces associated with power toothbrushes to cause biofilm removal from interproximal surfaces beyond bristle contact. The constant depth film fermenter (CDFF) has been shown to produce steady-state oral biofilm communities and plaque structures similar to those occurring in the mouth.[18,19] Application of the CDFF biofilm to the in vitro model described by Hope and Wilson provides a measure of the ability of an oral hygiene device to remove biofilm beyond the reach of the bristles. A brief summary of the methodology is provided below.

Treatment Arms

Three treatment arms were used in this test: the prototype integrated system toothbrush as the test device, the Oral-B® ProfessionalCare 7000[c] as a comparative rotating/oscillating power toothbrush, and a nonbrushing control. The devices were tested in the absence of toothpaste, as the components within the toothpaste could influence bacterial viability. Previous studies have shown that inactive power toothbrushes (toothbrush turned off) remove relatively little biofilm bacteria interproximally,[9,10] and thus inactive toothbrush treatment arms were not included in this study.

[b]The Procter & Gamble Co, Cincinnati, OH 45202; 800-492-7378
[c]Oral-B Laboratories, Boston, MA 02127; 800-446-7252

Specimen Preparation

Saliva samples collected from 20 individuals (ranging in age from 20 to 40 years and in good oral health) were processed and stored for use in inoculating the CDFF chambers. The CDFF chambers contained 75 hydroxyapatite (HA) disks[d] on which the biofilm was grown at a constant depth (200 µm). The biofilm was allowed to develop for 4 to 5 days of growth under aerobic conditions. Upon harvest, all HA disks from the CDFF were used in one run of the brushing experiment. A pan containing disks was removed as needed and immediately taken to the brushing apparatus, where the HA disks were removed and placed in sterile Ringer's irrigation solution for subsequent testing. Care was taken not to disturb the biofilm when removing the pans or manipulating the HA disks. Before use in the assay, each biofilm-coated HA disk was dipped without agitation in Ringer's irrigation solution to remove nonadherent bacteria.

Comparative information to alternative products allows the user to choose the product best suited to meet specific oral hygiene needs.

Brushing Experiments

Fully charged power toothbrushes were positioned with respect to the typodont tooth section according to instructions within the instruction manual of each product. Separation between the bristles and the interproximally located HA disks was ensured visually to be 1 mm to 2 mm as the active toothbrush was moved across the typodont. A pair of biofilm-coated HA disks were placed in interproximal recesses between representative mandibular molars, one on each side of the interproximal space flush with the surface of the tooth. In this location, the biofilm-coated HA disks represented plaque on the interproximal tooth surface. The exposure chamber was filled with 7 mL of diluted Saliva Substitute™[e] (33% v/v Ringer's) to mimic fluid levels at the dentition during a typical brushing.

Randomization of the treatment order for the biofilm-coated HA disks was performed by colleagues who were blind to the nature of treatments and outcomes. After each brushing (15 seconds for the 5-tooth typodont section), the fluid within the brushing chamber was completely removed using a disposable curved syringe. This fluid was considered to contain the biofilm bacteria removed as a result of fluid-induced forces of the toothbrush. The fluid was transferred to sterile 15-mL conical tubes, vortexed, and bath-sonicated for 2 minutes. The fluid was diluted 1:10 by adding 1 mL of fluid to 9 mL of sterile Ringer's irrigation solution. Aliquots of this dilution were then plated on tryptic soy agar plates supplemented with 5% sheep's blood using a spiral plater[f]. Plates were incubated aerobically at 37°C for 24 hours in 5% carbon dioxide before bacterial colonies were enumerated.

Each run of a CDFF yields 12 replicates per treatment arm. The study consisted of 3 runs of the CDFF for a total of 36 replicates per treatment arm. Colony-forming units (CFUs) were recorded for each of the replicates and normalized to the volume of brushing fluid sampled (CFU/mL) to represent the amount of biofilm removed with that test.

Analysis

The raw data in CFU/mL were transformed by the base-10 logarithm to create a more normal distribution as appropriate for the subsequent analysis of variance (ANOVA). In the ANOVA, log (CFU/mL) was the dependent variable and treatment group was the independent variable. The null hypothesis was that there is no difference in mean log (CFU/mL) between the three treatment arms. The alternative hypothesis was that at least two of the means differ.

Overall differences between treatments were tested with an F statistic at the $\alpha = 0.05$ level of significance. Multiple comparisons were conducted to specify where the differences exist, if so designated by the F test.

Mean CFU/mL per treatment also was calculated on the raw data for comparison of relative effects. The measure of difference between two treatments was calculated as the ratio of the difference in CFU/mL between one treatment and the nontreatment control to the difference in CFU/mL between the second treatment and the nontreatment control.

[d]Clarkson Chromatography Products, Inc, South Williamsport, PA 17702; 570-323-0450

[e]Roxane Laboratories, Inc, Columbus, OH 43216; 800-962-8364

[f]Spiral Biotech, Norwood, MA 02062; 800-554-1620

Table 1—[illegible]

Treatment Group	CFU/mL Mean (SD)	Log (CFU/mL) Mean (SD)	Homogeneous Group
No-treatment control	8.29×10^4 (5.52×10^4)	4.81 (0.31)	A
IntelliClean System (integrated system, toothbrush only)	2.37×10^6 (6.10×10^5)	6.36 (0.11)	B
Oral-B® ProfessionalCare 7000 (rotating/oscillating toothbrush)	5.69×10^5 (3.23×10^5)	5.68 (0.28)	C

*n = 36 each treatment arm.
†Groups in the same column are not statistically different at $P < .05$.
CFU = colony-forming units; SD = standard deviation.

Results

The results of the biofilm removal tests are shown in Table 1 and expressed in CFU/mL and log (CFU/mL). Each treatment was statistically different from the others ($P < .05$). The integrated system toothbrush removed the greatest amount of biofilm from the disk surfaces, 3.7 times more than the rotating/oscillating toothbrush based on the mean number of viable bacteria CFUs removed by each brush.

Dentin-Abrasion Experiments

Materials and Methods

The dentin-abrasion tests conducted closely followed the methodology employed by Sorensen and Nguyen.[17] This methodology was developed specifically for investigating dentin wear associated with the use of power and manual toothbrushes. It takes into consideration the bristle motion inherent in the operation of the toothbrush (eg, movement of the bristles by the toothbrush itself) as well as bristle motion resulting from the user (eg, movement of the toothbrush throughout the mouth). Furthermore, the methodology ensures accurate comparatives such that the dentin is exposed to the complete brush head for the same duration of exposure for all products. A brief summary of the methodology is provided below.

Treatment Arms

As outlined in Table 2, 4 treatment arms were included in the study with chosen parameters for device, toothpaste, and brush-head load. Devices consisted of the integrated system toothbrush as the test device, the Oral-B® ProfessionalCare 7000 as the comparative oscillating/rotating power toothbrush, and the Oral-B® Indicator® 35 manual toothbrush[c] as the control. The integrated system was tested with both the prototype standard and whitening liquid toothpastes; the comparative power toothbrush and the manual toothbrush were tested with only the prototype standard liquid toothpaste. As was described by Sorensen and Nguyen, different loads were used for each device based on available evidence of typical use patterns for these different toothbrush technologies.[17] Each arm consisted of a total of 12 specimens being exposed to treatment, randomized in blocks of 4 (the brushing machine simultaneously brushed 4 specimens of 1 treatment type).

Specimen Preparation and Brushing Experiments

Human dentin was sectioned from extracted teeth using a slow-speed saw with a diamond-wafering blade in a water bath, with cuts made to avoid pulp canals and chambers. The dentin sections were cut to 3 mm by 10 mm and embedded in a resin mold shaped to approximate the curvature of teeth. The surface (dentin section and specimen face) was polished flat, with the exception of the valleys between the representative tooth ridges. Specimens were scanned with a profilometer to

Table 2—Treatment Groups for Dentin Abrasion Study

Group	Toothbrush	Toothpaste	Brush-head Load (g)
1	IntelliClean System (integrated system)	IntelliClean	90
2	IntelliClean System	IntelliClean plus Whitening	90
3	Oral-B® ProfessionalCare 7000 (rotating/oscillating)	IntelliClean	150
4	Oral-B® Indicator® 35 (manual)	IntelliClean	250

Treatment Group*	Toothpaste	Average Depth (Mean [SD])	Homogeneous Group†
IntelliClean System (integrated system)	IntelliClean	28.0 (7.2)	A
IntelliClean System	IntelliClean plus Whitening	40.6 (14.1)	A
Oral-B® ProfessionalCare 7000 (rotating/oscillating)	IntelliClean	80.1 (27.8)	B
Oral-B® Indicator® 35 (manual)	IntelliClean	67.8 (17.0)	B

*n = 12 each treatment arm.
†Groups in the same column are not statistically different at $P < .05$.
SD = standard deviation.

ensure a smooth surface and were kept hydrated before use. The specimens were randomly assigned to toothbrush treatment groups.

All power toothbrush handles were externally powered so that operating characteristics remained consistent throughout the brushing episode without concern of depleting the batteries. The brush-head motion of the externally powered toothbrushes used in the test was verified to match that of the same brushes before they were altered with the external power leads. The brushes were mounted on a brushing machine so that the complete brush head would move back and forth across the dentin section within the specimen at a constant velocity. This avoided an active brush head dwelling over the dentin section as the machine reversed direction. A new brush head was used for each of the 12 replicates within a treatment arm. A slurry of 0.5 part toothpaste, 0.8 part water, and 1 part artificial saliva (by mass) determined by the treatment arm was applied at a controlled drip (50 mL/min).

Brush exposure on the dentin section approximated an equivalent 2-year typical use of two, 2-minute brushings per day. For the power toothbrushes, this resulted in 52 minutes of brushing per dentin-section surface. For the manual toothbrush, 12,500 strokes across the dentin section represented typical use assuming the user's hand brushes at approximately 2 Hz.

Analysis

Wear on the dentin substrate was evaluated using a profilometer. An impartial individual who was blind to the treatment assignment performed the dentin-wear surface analysis. Scans were taken in triplicate, perpendicular to the brushing machine's motion and at a distance of 1 mm apart. Every set of scans contained a control scan of the unbrushed portion on both sides of the wear facet of the specimen, serving as a reference. The average depth and average maximum depth of the three profiling scans were calculated for each sample across the complete dentin section, followed by the calculation of mean depth and mean maximum depth for each condition based on 12 specimens for each condition.

The quantitative data were analyzed with a one-way ANOVA, with wear as the dependent variable and treatment group as the independent variable. The null hypothesis was that there is no difference in mean dentin wear between the four treatment arms. The alternative hypothesis was that at least two of the means differ.

Differences between treatments were tested with an F statistic at the $\alpha = 0.05$ level of significance. Multiple comparisons were conducted to specify where the differences exist, if so designated by the F test.

Table 4—Average Maximum Depth of Toothbrush/Toothpaste-induced Dentin Substrate Wear (µm)

Treatment Group*	Toothpaste	Average Maximum Depth (Mean [SD])	Homogeneous Group†
IntelliClean System (integrated system)	IntelliClean	55.9 (16.8)	A
IntelliClean System	IntelliClean plus Whitening	79.1 (22.1)	A
Oral-B® ProfessionalCare 7000 (rotating/oscillating)	IntelliClean	149.1 (43.7)	B
Oral-B® Indicator® 35 (manual)	IntelliClean	129.2 (23.7)	B

*n = 12 each treatment arm.
†Groups in the same column are not statistically different at $P < .05$.
SD = standard deviation.

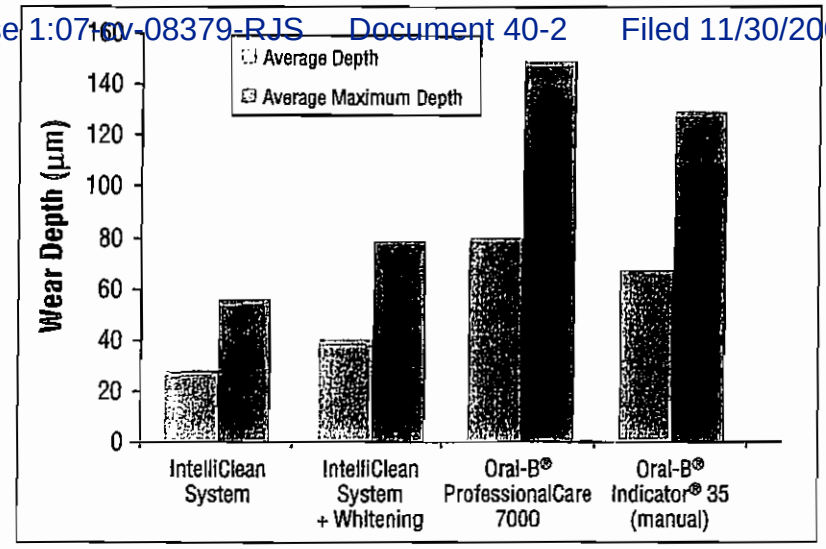

Figure 1—Average and average maximum depths of wear (µm) for each treatment group.

Results

The results of the dentin-abrasion tests can be found in Table 3 (average wear), Table 4 (maximum wear), and Figure 1. For both measures, the two integrated-system treatment groups produced significantly less wear than the rotating/oscillating toothbrush and the manual toothbrush ($P < .05$). There were no significant differences between the two toothpaste arms for the integrated system. Similarly, there were no significant differences between the manual toothbrush and the rotating/oscillating toothbrush.

Discussion

Dental plaque commonly forms on tooth surfaces within the oral cavity. Plaque accumulates preferentially in regions sheltered from the physical forces that may disrupt its adherence. These regions include interproximal spaces, the sulcus, the gumline, and pits and fissures of the tooth structure. Traditionally, the primary means by which a toothbrush cleans the tooth surface is by bristle contact. The direct contact of the bristle with the tooth displaces dental plaque and aids in its removal from the oral cavity. This bristle-to-tooth contact, therefore, limits cleaning to areas directly teached by the bristles. Cleaning and polishing of the tooth surface is aided by toothpaste that may, in part, contribute to wear of the tooth surface, particularly the softer dentin and cementum structures.

In contrast to traditional brushes that rely primarily on direct bristle contact for cleaning, Sonicare® technology has been shown to remove biofilm bacteria beyond the reach of the bristles. The rapid motion of the Sonicare® bristles activates fluid surrounding the brush head, forcing it into regions the bristles do not contact. This fluid motion effects biofilm removal.[7,9-11] Because the rapidly moving bristles function to clean the tooth surface, users typically apply less force than they would with a manual toothbrush.

With respect to the removal of plaque biofilm beyond the reach of the bristles, the current results with the prototype integrated-system toothbrush are consistent with previously published work in which fluid activity associated with the Sonicare® toothbrush was found to remove more biofilm in the interproximal space of this in vitro model than a power toothbrush with rotating/oscillating motion.[10,11] Results presented here demonstrate nearly four times greater removal of biofilm bacteria with the prototype integrated-system toothbrush. This demonstrated superiority is likely a result of the magnitude of the fluid motion generated by the toothbrush and its direction. The toothbrush propels fluid between the teeth as opposed to the rotating/oscillating toothbrush, which generates less fluid motion and generally propels fluid along the smooth surfaces of the teeth (facial or lingual aspect).

Previous studies using this methodology have indicated that this beyond-the-bristles biofilm removal effect was because of the fluid motion generated by the active motion of the bristles (ie, when the bristles were inactive, there was very little removal of biofilm, likely as a result of the minor agitation of fluid as the inactive brush is moved back and forth across the teeth).[10,11] In the current study, a nonbrushing treatment served as a control as opposed to the inactive toothbrush. The biofilm bacteria removed in this control arm represent the spontaneous release of bacteria from the biofilm surface as a result of forces associated with handling the biofilm within a fluid environment. This effect is minimal compared to that of the active prototype or rotating/oscillating toothbrushes.

In the dentin-abrasion study, the prototype integrated system was found to be less abrasive

than the manual toothbrush and the rotating/oscillating toothbrush used with the prototype standard liquid toothpaste. This is consistent with previous results that showed the Sonicare® technology to yield the least amount of dentin wear.[17] No statistical difference was found between the standard and whitening versions of the liquid toothpaste.

The in vitro test methods applied here provide objective analyses of the efficacy and safety of these oral hygiene products. Both the biofilm and dentin-wear experiments have been developed for power toothbrush evaluation, taking into consideration the inherent bristle motion of the device as well as the motion required to move the toothbrush across the tooth surface. They provide methods of assessment of product efficacy representative of what would be found in the oral cavity. These methods build on previous in vitro work within the dental community in which basic models were used to evaluate toothbrush performance[6,8] and dentin wear associated with manual toothbrushes and toothpastes.[20,21]

Conclusion

The IntelliClean System toothbrush, with its associated dynamic fluid activity, demonstrates superior removal of biofilm as compared to a power toothbrush with conventional rotating/oscillating bristle motion. Furthermore, the IntelliClean System with both standard and whitening toothpastes demonstrates significantly lower levels of dentin abrasion than a power toothbrush with rotating/oscillating motion and a manual toothbrush. The results presented here validate that the IntelliClean System is both safe and efficacious and provide the consumer and dental professional with information allowing an informed choice in oral hygiene product selection.

Disclosure

This research was supported by Philips Oral Healthcare, Inc.

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PG007104